

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

To:

FRANK B. DEHN & CO.
179 Queen Victoria Street
London EC4V 4EL
UNITED KINGDOM

Date of mailing
(day/month/year)

22/02/2001

Applicant's or agent's file reference

97.69959/001

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/GB 00/03089

International filing date
(day/month/year)

10/08/2000

Applicant

NOVARTICULATE HOLDINGS LIMITED et al.

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Stefan Filus

TENT COOPERATION TREAT

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 97.69959/001	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/ 03089	International filing date (day/month/year) 10/08/2000	(Earliest) Priority Date (day/month/year) 10/08/1999
Applicant NOVARTICULATE HOLDINGS LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 00/03089

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 46-54
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-11, 13-18, 20, 27-32, 35-38, 40

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-11,13-18,20,27-32,35-38,40

apparatus for positioning and cementing a component of or for a prosthesis, comprising means for positioning the component (or a tool to which the component is releasably mountable); cement delivery means (and a seal carried by the cement delivery means)

2. Claims: 12,21-26

a joint prosthesis for replacing the socket of a ball and socket joint, wherein the cup-shaped component has apertures through which cement may be provided.

3. Claim : 19

apparatus for positioning a component comprising a seal and a passage for withdrawing air from the space defined by sealed surfaces.

4. Claims: 33,34

apparatus for delivering fluid to a cavity in a bone and for sealing a cavity, comprising a seal ring being carried or confined within the radial dimensions of an elongated housing


5. Claim : 39

apparatus for cementing a prosthetic component in place, comprising cement delivery means and a balloon, the balloon carried by a part through which cement is supplied

6. Claims: 41-45

apparatus for delivery cement around a component comprising plural nozzles to simultaneously provide cement at different circumferential locations around the component.

INTERNATIONAL SEARCH REPORT

International Application No
 /GB 00/03089

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 082 072 A (BROWN BYRON L) 3 March 1982 (1982-03-03)	1,2,4-7, 10,13, 19,20
Y	page 3, line 90 - line 92 page 4, line 6 - line 117; claims 1,3,8; figure 1	8,9
Y	--- DE 38 35 853 A (GMT MEDIZINISCHE TECHNIK GMBH ; TECHNOLAS LASER TECHNIK GMBH (DE)) 26 April 1990 (1990-04-26) column 1, line 3 - line 26 column 3, line 32 - line 37	8
Y	--- US 5 591 171 A (BROWN BYRON L) 7 January 1997 (1997-01-07)	9
A	column 5, line 17 - line 20 --- -/--	27,35,37

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

14 December 2000

Date of mailing of the international search report

22.02.01

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Arjona Lopez, G

INTERNATIONAL SEARCH REPORT

International Application No

/GB 00/03089

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 197 22 923 A (CERAMTEC AG INNOVATIVE CERAMIC) 13 August 1998 (1998-08-13) abstract column 3, line 48 - line 53; figure 1 ---	3,7,13, 15-18
A	WO 98 15240 A (SMITH & NEPHEW INC) 16 April 1998 (1998-04-16) abstract; figure 7 ---	3,11
A	EP 0 393 425 A (SQUIBB BRISTOL MYERS CO) 24 October 1990 (1990-10-24) column 8, line 15 - line 34; figure 12 ---	11
A	WO 95 22286 A (DEPUY INT LTD ;COHEN ANDREW (GB); DAVIES HUGH (GB); ISAAC GRAHAM ()) 24 August 1995 (1995-08-24) abstract page 1, paragraph 4; figures 1,5 ---	14
A	US 5 468 245 A (VARGAS III JOSEPH H) 21 November 1995 (1995-11-21) abstract; figure 20 ---	27,28
A	US 4 627 434 A (MURRAY WILLIAM M) 9 December 1986 (1986-12-09) figures 11,12 -----	28,29

INTERNATIONAL SEARCH REPORT

Information on patent family members



International Application No

/GB 00/03089

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 2082072	A	03-03-1982	US 4357716 A	09-11-1982
DE 3835853	A	26-04-1990	NONE	
US 5591171	A	07-01-1997	NONE	
DE 19722923	A	13-08-1998	NONE	
WO 9815240	A	16-04-1998	US 5931870 A	03-08-1999
			AU 4606897 A	05-05-1998
			EP 0948298 A	13-10-1999
EP 0393425	A	24-10-1990	DE 3912465 C	08-11-1990
			AT 94369 T	15-10-1993
			DE 59002694 D	21-10-1993
			ES 2044290 T	01-01-1994
			US 5116377 A	26-05-1992
WO 9522286	A	24-08-1995	AU 684979 B	08-01-1998
			AU 2971595 A	04-09-1995
			DE 69503360 D	13-08-1998
			DE 69503360 T	01-04-1999
			EP 0744917 A	04-12-1996
			ES 2118565 T	16-09-1998
			ZA 9501211 A	23-10-1995
US 5468245	A	21-11-1995	NONE	
US 4627434	A	09-12-1986	US 4625722 A	02-12-1986

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 97.69959/001		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/03089	International filing date (day/month/year) 10/08/2000	Priority date (day/month/year) 10/08/1999	
International Patent Classification (IPC) or national classification and IPC A61F2/46			
Applicant NOVARTICULATE HOLDINGS LIMITED et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input checked="" type="checkbox"/> Certain defects in the international applicationVIII <input checked="" type="checkbox"/> Certain observations on the international application			
Date of submission of the demand 06/03/2001		Date of completion of this report 12.11.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 eprnu d Fax: +49 89 2399 - 4465		Authorized officer Arjona Lopez, G Telephone No. +49 89 2399 2546 	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03089

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-29 as originally filed

Claims, No.:

1-54 as originally filed

Drawings, sheets:

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03089

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 3,11,12,14,19,21-26,33,34,39,41-54.

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 3,11,14 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 12,19,21-26,33,34,39,41-54.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 8,9,15-18,27-32,35-38,40

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03089

	No:	Claims	1-2,4-7,10,13,20
Inventive step (IS)	Yes:	Claims	15-18,27-32,35-38,40
	No:	Claims	1-2,4-7,10,13,20
Industrial applicability (IA)	Yes:	Claims	1-2,4-10,13,20
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03089

To point III:

1. See the reasons for the lack of clarity under point VIII-1.2 and 1.4 below.
- 1.1 In particular, since it is not clear which technical features the apparatus should have, so that it can be used with a cup component of an artificial hip prosthesis, no examination has been done of the subject-matter of claim 3.

To point V:

1. Reference is made to the following documents:

D1: GB-A-2 082 072
D2: DE-A-3 835 853
D3: US-A-5 591 171
2. Document D1, which is considered to represent the most relevant state of the art, discloses (cf. figures 1,4b,5d; page 1, lines 5-7; page 3, lines 83-92; page 4, lines 6-117; claims 1,3,8) an apparatus for positioning and cementing a component of or for a prosthesis (femoral stem prosthesis 162), the apparatus comprising means for positioning the component (base guide 10, lid clamp 16) in or adjacent a bone cavity (femoral canal 164), cement delivery means (separator-sealer device 12, ceiling 14) for providing cement under pressure to a cavity space (164) next to the component whilst the component is in its desired position, and a seal (separator sealer 12) carried by the cement delivery means (12,14) and arranged to confine the cement in such space until it has set.
- 2.1 The subject-matter of claim 1 is therefore not novel (Article 33(2) PCT).
3. Dependent claims 2,4,7-10,13,20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

3.1 Claim 2: In Document D1, the component is a part of a femoral stem prosthesis

for mounting in the femoral canal. The subject-matter of claim 2 is therefore not new, as far as it can be understood (cf. point VIII-1.2 below);

- 3.2 Claim 4: Document D1 further discloses, that the means for positioning the component comprises a tool (lid clamp 16) provided with carrying means (two halves 116,118) on which the component for the prosthesis is releasably mounted. The subject-matter of claim 4 is therefore not new;
- 3.3 Claim 7: Document D1 (cf. especially figures 5d,10b; page 8, lines 88-99) also discloses, that the tool includes an elongate, tubular housing (filling device 250) and that the means for releasably mounting the component (16) is provided at the distal end of the housing (250). The subject-matter of claim 7 is therefore not new;
- 3.4 Claims 8-9: To provide the apparatus of claim 1 with an endoscope (cf. for example D2, column 1, line 3-26) or with a pressure transducer (cf. for example D3, figures 1-2; abstract; column 3, lines 36-38) are usual constructive measures. The subject-matter of claims 8 and 9 is therefore not inventive;
- 3.5 Claim 10: Document D1 (cf. especially figure 5d; claim 8(b); page 4, lines 71-74) further discloses means for forcing cement under pressure (first orifice 98) , through a tube (cement syringe), and into the space defined by the cavity and the component and confined by the seal. The subject-matter of claim 10 is therefore not new;
- 3.6 Claim 13: The apparatus of D1 (cf. especially figure 8a; page 7, lines 47-61) also comprises a mating part (16) engageable with the component and locking means (bolts) for releasably locking the component thereto. The subject-matter of claim 13 is therefore not new;
- 3.7 Claim 20: cement delivery orifices in the apparatus of claim 1 have also been disclosed in D1 (cf. claim 8). As this is the only features of claim 1 that refers to the apparatus (cf. point VIII-1.2 and 1.5 below), the subject-matter of claim 20 is regarded as not being new.
4. Document D1 is also considered to represent the closest prior art for the subject-

matter of independent claim 5, as far as this can be understood (cf. point VIII-1.3 below) and it discloses an apparatus for positioning a component of or for a prosthesis, the apparatus comprising a tool (cf. figures 1,5d; reference numbers 10,12,14,16) having a distal end (at 14 and 16) to which the component is releasably mountable such that the component is fixed to the tool (10,12,14,16) and can be carried and manipulated thereby, wherein the tool also has cement delivery means (12,14) for cementing the component in a cavity (164) in a bone within the body whilst the component is still mounted to the tool (10,12,14,16) and positioned thereby.

- 4.1 The subject-matter of claim 5 is therefore not new.
5. Document D1 further discloses a seal (12) for confining the cavity in which the component is to be cemented. The subject-matter of dependent claim 6 is therefore not new.
6. The subject-matter of dependent claim 15 differs from the known apparatus of D1 in that, the locking means comprises means for attaching the component to the mating part tool by suction. This features cannot be rendered obvious in the light of the available prior art, since applying this features to the known apparatus in order to quickly lock and unlock the component, would require cumbersome modifications of respective parts of the known apparatus. The subject-matter of claim 15 is therefore new and inventive (articles 33(2) and (3) PCT).
7. Claims 16 to 18 are dependent on claim 15 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
8. The subject-matter of dependent claim 27 differs from the known apparatus of D1 in that, the seal is a generally annular or doughnut shape extending around the cement delivery means. This features cannot be rendered obvious in the light of the features of the known apparatus. Modifying the seal should also require to modify all the therewith cooperating parts like the ceiling 14 and therefore the lid clamp 16, so that a completely different apparatus would result. The subject-matter of claim 27 is therefore new and inventive (articles 33(2) and (3) PCT).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03089

9. Claims 28 to 32, 35 to 38 and 40 (when depending on claims 27 to 33) are dependent on claim 27 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

To point VII:

1. Any independent claim should have been in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would have been appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
2. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. In accordance with the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 should have been mentioned in the description and this document should have been identified therein.
4. According to the requirements of Rule 11.13(m) PCT the same feature should have been denoted by the same reference sign throughout the application. This requirement is not met in view of the use of feature "O-ring seal" (cf. page 25, line 4) and feature "fluid passage" (cf. page 26, line 11), since the reference sign 105 applies to both features. Similar applies to the features "apertures" and "annular seal" and reference sign 78 (cf. page 24, lines 15,18).

To point VIII:

1. The subject-matter of following claims is not clearly defined, for the following reasons:
 - 1.1 Although claims 1 and 5 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter (for example, claim 6, dependent on claim 5 comprises all the features of independent claim 1) and to differ from each other only with regard to the definition of the subject-matter for

which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection;

- 1.2 Dependent claims 2,3,11 do not define any further technical features of the apparatus of claim 1, since they just define features of the intended use (i.e, that the component is a cup component of a joint prosthesis or of an artificial hip prosthesis in claims 2 and 3, or that the cement is supplied via one or more apertures in the component itself in claim 11);
- 1.3 The following wording, in particular the use of "or", renders the subject-matter of claim 5 unclear "wherein the tool also has cement delivery means for cementing the component ~~or~~ in a cavity in a bone within the body". For the purpose of the examination, this sentence has been interpreted as "wherein the tool also has cement delivery means for cementing the component in a cavity in a bone within the body";
- 1.4 Dependent claim 14 is dependent on claim 13, that is itself dependent of any claim 1 to 11. Nevertheless claim 14 refers to a cup component that has been only defined on claim 3, so that only the dependence of claim 13 with respect to claim 3 would renders the subject-matter of claim 13 clear. Nevertheless, the subject-matter of claim 3 is not clear (cf. point VIII-1.1 above). Therefore, the subject-matter of claim 14 is not clear either;
- 1.5 Dependent claim 20 is dependent on any of the claims 1 to 11 or 13 to 19. Nevertheless this claim refers to a tool, that was firstly defined in claim 4. Therefore, the dependence of claim 20 with respect to claim 1 to 3, 8 to 11, 13 to 19 renders the subject-matter of claim 20 unclear.
- 1.6 Dependent claims 37 and 38 refer to "the tool of any of claims 28 to 36", while claims 28 to 36 define no tool but an apparatus. Besides the special features of claim 37 refers to a balloon that has been firstly defined in claim 36 and not in

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03089

claims 28 to 35, therefore reference to claims 28 to 35 leads the reader to confusion. In order to carry out the examination "the tool" has been understood as meaning "the apparatus".

(19) World Intellectual Property Organization
International Bureau



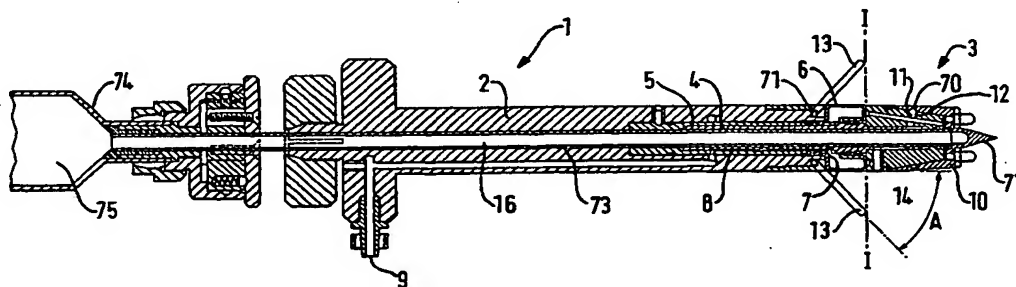
(43) International Publication Date
15 February 2001 (15.02.2001)

PCT

(10) International Publication Number
WO 01/10356 A3

- (51) International Patent Classification⁷: **A61F 2/46**
- (21) International Application Number: **PCT/GB00/03089**
- (22) International Filing Date: **10 August 2000 (10.08.2000)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
9918884.9 **10 August 1999 (10.08.1999)** **GB**
- (71) Applicant (for all designated States except US): **NOVARTICULATE HOLDINGS LIMITED [GB/GB]; P.O. Box 42, Sandy, Bedfordshire SG19 2XT (GB).**
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **VERDON SCHOT, Nicolaas, Jacobus, Joseph [NL/NL]; Fransestraat 22, NL-6524 JB Nijmegen (NL). KRIEK, Hans, Rudolf [NL/NL]; Ruthardlaan 36, NL-1406 RT Bussum (NL). WILLEMS, Maria, Margaretha, Martina [NL/NL]; Dept. of Orthopaedics, Katholieke Universiteit Nijmegen, Th. Craanenlaan 7, NL-6500 HN Nijmegen (NL). JANSSEN, Bernardus, Johannes, Elisabeth, Maria [NL/NL]; Dept. of Instrumental Services, Katholieke Universiteit Nijmegen, Th. Craanenlaan 7, NL-6500 HN Nijmegen (NL). VAN DE WIJDEVEN, Wilhelmus, Servatius, Johannes [NL/NL]; Dept. of Orthopaedics, Katholieke Universiteit Nijmegen, Th. Craanenlaan 7, NL-6500 HN Nijmegen (NL).**
- (74) Agent: **FRANK B. DEHN & CO.; 179 Queen Victoria Street, London EC4V 4EL (GB).**
- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (regional): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).**
- Published:
— with international search report
- (88) Date of publication of the international search report:
23 August 2001
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **METHOD AND APPARATUS FOR DELIVERING CEMENT TO BONES AND/OR POSITIONING COMPONENTS**



(57) Abstract: A cement delivery device (1), having a generally elongate construction, is provided. The cement delivery device (1) has main body (2) with a placement head (3) mounted at a distal end of the body (2) arranged to fit with a cup shaped component (10) of a joint prosthesis. Tubes (4) and (5) form part of a cement delivery passage (16) along the longitudinal central axis of the cement delivery device (1). Between the head (3) and the body (2), an annular seal (6) extends around the tube (4) of the head (3), which seal is collapsible and expandable to facilitate insertion of the device (1) through a narrow opening or bore and subsequent expansion of the seal to suitable dimensions when the device (1) has been inserted. The seal (6) comprises an annular or doughnut shaped balloon (6) extending around the tube (4). A tool is also provided for placement of a component in a cavity in a bone, which tool carries an annular seal similar to that of the cement delivery device (1), but which is used to place a component in and seal a cavity in which cement has already been provided.

WO 01/10356 A3

INTERNATIONAL SEARCH REPORT

International Application No

GB 00/03089

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 082 072 A (BROWN BYRON L) 3 March 1982 (1982-03-03)	1,2,4-7, 10,13, 19,20
Y	page 3, line 90 - line 92 page 4, line 6 - line 117; claims 1,3,8; figure 1	8,9
Y	--- DE 38 35 853 A (GMT MEDIZINISCHE TECHNIK GMBH ; TECHNOLAS LASER TECHNIK GMBH (DE)) 26 April 1990 (1990-04-26) column 1, line 3 - line 26 column 3, line 32 - line 37	8
Y	--- US 5 591 171 A (BROWN BYRON L) 7 January 1997 (1997-01-07)	9
A	column 5, line 17 - line 20 --- -/--	27,35,37

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

*** Special categories of cited documents :**

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

14 December 2000

Date of mailing of the international search report

22 02 01

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Arjona Lopez, G

INTERNATIONAL SEARCH REPORT

International Application No

GB 00/03089

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 197 22 923 A (CERAMTEC AG INNOVATIVE CERAMIC) 13 August 1998 (1998-08-13) abstract column 3, line 48 - line 53; figure 1 ---	3,7,13, 15-18
A	WO 98 15240 A (SMITH & NEPHEW INC) 16 April 1998 (1998-04-16) abstract; figure 7 ---	3,11
A	EP 0 393 425 A (SQUIBB BRISTOL MYERS CO) 24 October 1990 (1990-10-24) column 8, line 15 - line 34; figure 12 ---	11
A	WO 95 22286 A (DEPUY INT LTD ;COHEN ANDREW (GB); DAVIES HUGH (GB); ISAAC GRAHAM ()) 24 August 1995 (1995-08-24) abstract page 1, paragraph 4; figures 1,5 ---	14
A	US 5 468 245 A (VARGAS III JOSEPH H) 21 November 1995 (1995-11-21) abstract; figure 20 ---	27,28
A	US 4 627 434 A (MURRAY WILLIAM M) 9 December 1986 (1986-12-09) figures 11,12 -----	28,29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 00/03089

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **46-54**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-11, 13-18, 20, 27-32, 35-38, 40

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-11,13-18,20,27-32,35-38,40

apparatus for positioning and cementing a component of or for a prosthesis, comprising means for positioning the component (or a tool to which the component is releasably mountable); cement delivery means (and a seal carried by the cement delivery means)

2. Claims: 12,21-26

a joint prosthesis for replacing the socket of a ball and socket joint, wherein the cup-shaped component has apertures through which cement may be provided.

3. Claim : 19

apparatus for positioning a component comprising a seal and a passage for withdrawing air from the space defined by sealed surfaces.

4. Claims: 33,34

apparatus for delivering fluid to a cavity in a bone and for sealing a cavity, comprising a seal ring being carried or confined within the radial dimensions of an elongated housing

5. Claim : 39

apparatus for cementing a prosthetic component in place, comprising cement delivery means and a balloon, the balloon carried by a part through which cement is supplied

6. Claims: 41-45

apparatus for delivery cement around a component comprising plural nozzles to simultaneously provide cement at different circumferential locations around the component

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

GB 00/03089

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 2082072	A	03-03-1982	US 4357716 A	09-11-1982
DE 3835853	A	26-04-1990	NONE	
US 5591171	A	07-01-1997	NONE	
DE 19722923	A	13-08-1998	NONE	
WO 9815240	A	16-04-1998	US 5931870 A	03-08-1999
			AU 4606897 A	05-05-1998
			EP 0948298 A	13-10-1999
EP 0393425	A	24-10-1990	DE 3912465 C	08-11-1990
			AT 94369 T	15-10-1993
			DE 59002694 D	21-10-1993
			ES 2044290 T	01-01-1994
			US 5116377 A	26-05-1992
WO 9522286	A	24-08-1995	AU 684979 B	08-01-1998
			AU 2971595 A	04-09-1995
			DE 69503360 D	13-08-1998
			DE 69503360 T	01-04-1999
			EP 0744917 A	04-12-1996
			ES 2118565 T	16-09-1998
			ZA 9501211 A	23-10-1995
US 5468245	A	21-11-1995	NONE	
US 4627434	A	09-12-1986	US 4625722 A	02-12-1986

METHOD AND APPARATUS FOR DELIVERING
CEMENT TO BONES AND/OR POSITIONING COMPONENTS

5 This invention relates to cement delivery and, more particularly, to a method and apparatus for delivering cement and the like to bones in the human and animal body. It also relates to positioning components to be cemented in place.

10 It is a well known to cement various types of prostheses or components to or in bones in the human and animal body. Likewise, treatment of bones that have been broken or are diseased may involve cementing bone together or filling a cavity in the bone. This
15 invention is particularly applicable to the delivery of cement or the like to cavities or bores in bones (whether natural or artificial) and to the fixation of prostheses or components in such cavities or bores where desirable.

20 Problems with conventional techniques for cement delivery can be understood by considering the replacement of worn out, damaged or diseased joints in human and animal bodies with artificial joint prostheses. Such prostheses may comprise, for example,
25 a replacement joint articulation, such as a metal ball and socket or other pivotal connection. Alternatively, the joint prosthesis may replace only part of the joint. For example, the ball of a ball and socket joint may be replaced with a joint prosthesis comprising an
30 artificial replacement ball designed to sit in the original socket of a natural joint or the socket of a ball and socket joint may be replaced with a joint prosthesis comprising an artificial socket designed to fit the original ball.

35 Regardless of whether the joint prosthesis replaces all or part of a joint, the joint prosthesis or parts of the joint prosthesis, need to be anchored in or located

- 2 -

on bone adjacent or near to the joint. Joint prostheses therefore generally further comprise means for anchoring the replacement articulation, joint surface or joint part in a bone. For example, a joint prosthesis for replacing a ball and socket joint, such as the human shoulder or hip, often has a replacement articulation comprising a ball and socket. The replacement ball may be located on, or formed integrally with, anchoring means comprising a pin arranged to be inserted in the medullary canal of a bone, such as the femur or humerus, after the natural ball has been removed. Similarly, a replacement socket may be carried in anchoring means comprising a cup which is arranged to fit in the bone surrounding the socket, such as the acetabulum or scapula, or carried on anchoring means comprising a pin which is inserted into an artificial bore in the acetabulum or scapula. Prosthesis components such as these anchoring means are usually cemented into the bone in their respective positions. This is generally achieved by applying cement to the area, cavity or both in which the anchoring means is to be fixed, then positioning the prosthesis component into the cement and holding it in position until the cement sets.

The cementing process in this type of procedure gives rise to a number of problems. Firstly, by its nature cement must set after a given time in its desired location, and this unavoidably puts a time constraint on the procedure between delivery of the cement the time after which the cement sets. For example, many cements are formed by mixing together two constituents to form a composition which sets after a given length of time due, for example, to a chemical reaction such as polymerisation (although cements may be made in other ways and have other constituents such as antibiotic ingredients to prevent infections, Hydroxyl Apatite or heavy elements to aid X-ray imaging for example). Thus, in a conventional procedure, in particular because the

prosthesis or component to be cemented is only positioned after cement has been applied, a surgeon has only the given time to insert the cement and the prosthesis component into position and any mistake or delay may lead to the procedure, in particular correct positioning, not being completed before the cement sets.

Another problem is that the cement should preferably be pressurised in order to force the cement into any cavities and recesses in the region which the cement is intended to fill and to help expel body fluids from that region. However, it can be very difficult to pressurise the cement and, at the same time, position the prosthesis component correctly. Thus, the cement may not be properly pressurised and body fluids may not be properly expelled on pressurisation or may re-enter the area or cavity as the component is being positioned. Such body fluids can weaken the cement fixation and the mounting of the component in the bone.

According to a first aspect of the present invention there is provided apparatus for positioning and cementing a component of or for a prosthesis, the apparatus comprising means for positioning the component in or adjacent a bone cavity, cement delivery means for providing cement under pressure to a cavity space next to the component whilst the component is in its desired position, and a seal carried by the cement delivery means and arranged to confine the cement in such space until it has set.

A further aspect of the invention provides a method of cementing a component of or for a prosthesis into or adjacent a bone cavity, comprising locating the component in a desired position, providing a seal, and providing cement under pressure into a cavity space next to the component and confined by the seal.

Preferably, the provision of cement comprises the provision of cement using a cement delivery means and the provision of a seal comprises locating over a cavity

- 4 -

a seal carried by the cement delivery means and preferably the method also comprises removing the seal when the cement has set.

Thus, a component for a prosthesis such as an
5 anchoring means, or a joint prosthesis component itself, is positioned in or adjacent a bone cavity before the cement is delivered. This enables correct positioning to be achieved without any undue time constraint caused by the cement setting time.
10 Furthermore, cement pressurisation may be carried out with the component in its intended final position, and the pressure can be maintained by the seal until the cement sets. More reliable pressurisation can therefore be achieved and there is less chance of body
15 fluid remaining in the cavity space in which the cement is intended to be located and interfering with fixation of the cement to the surrounding bone. The method and apparatus of the invention are therefore more convenient to use and potentially provide more reliable fixation
20 than the prior art.

The invention is applicable to a wide range of components for placement in the human or animal body, including components for prostheses, e.g. joint replacement prostheses, such as separate anchoring parts
25 or articulating prosthetic parts themselves. The bone cavity into which the component is cemented will vary depending on the component or prosthesis concerned, and may be formed in or comprise a naturally occurring cavity such as a bone canal, recess, indentation or
30 socket, or it may be a cavity which is drilled or reamed by a surgeon especially for location of a prosthesis component. The invention is described below in relation to the anchoring of a cup component in the acetabular socket for an artificial hip prosthesis but, it will be
35 recognised, has wider application.

The invention may find particular utility in minimally invasive joint replacement procedures, such as

- 5 -

that described in WO98/34567. In such minimally
invasive procedures it is desirable to insert or locate
joint prostheses, or components of such joint
prostheses, through an incision distal from the joint,
5 and in the example described in WO98/34567, through a
bore in a bone. Thus, access to the location in which
the component is to be positioned is restricted, and it
is difficult to supply cement and to position the
prosthetic component correctly in the time it takes for
10 the cement to set. There is therefore an increased risk
of mis-location.

A preferred embodiment of the apparatus therefore
comprises a tool provided with carrying means on which
the component for the prosthesis is releasably mounted.
15 The component may therefore be positioned by
manipulating the tool and held in position thereby until
the cement has set, whereupon the component is released
from the carrying means. Thus, the component may be
guided and manipulated from a position remote from where
20 the component is to be mounted in a body.

Viewed from a still further aspect the invention
provides a placement tool for positioning a component of
or for a prosthesis, the tool comprising means for
detachably mounting the component to a distal end of the
25 tool such that the component is fixed to the tool and
can be carried and manipulated thereby, and means for
delivering cement for cementing the component on or in a
bone within the body whilst the component is still
mounted to the tool and positioned thereby.

30 The tool preferably also comprises a seal as well
as cement delivery means so that it provides the triple
function of locating the prosthetic component in its
desired position, providing a seal adjacent the
component, and supplying cement to the cavity space
35 surrounding the component and confined by the seal. The
tool may include an elongate, preferably tubular
portion, provided at its distal end with the carrying

means for the prosthetic component.

This represents a new departure from the prior art and has significant advantages. The tool may be manipulated manually by a surgeon, or its guidance may
5 be partly or entirely automated. It may be provided with suitable means, such as an endoscope, for providing the surgeon with an image of the site of the prosthesis to assist guidance and location. This may be particularly important in minimally invasive procedures
10 where the surgeon's view of the site is obscured.

Similarly, the tool may be provided with temperature and pressure transducers to either aid automation or to assist a surgeon in noting the pressure being applied on the tool or the temperature of the
15 cement as it sets. This is particularly useful where a surgical procedure is carried out robotically as the temperature and pressure transducers may provide feedback for a computer automation system.

The cement delivery means may comprise a tube,
20 carried by or extending through the tool, through which cement can be provided. Thus, cement may also be provided from a location distal from the position at which the component is to be mounted. Suitable means, such as a piston/cylinder device, may be provided to
25 force cement under pressure, through the tube, and into the bone cavity space around the component and confined by the seal.

The cement may be supplied to the space surrounding the prosthetic component via a suitable aperture in the
30 seal, which aperture would communicate with the cement delivery tube of the tool.

However, in a preferred embodiment which is particularly applicable to generally cup-shaped components of or for prostheses, the cement is
35 preferably supplied via one or more apertures in the component itself. In this way, an uninterrupted and unapertured seal may extend around the prosthetic

- 7 -

component, with the cement being introduced into the space around the component and confined by the seal, through the component.

5 This represents a new departure from the prior art, and a further aspect of the invention provides a cup-shaped component of or for a prosthesis, which component is intended to be cemented in position, and which includes one or more apertures which are arranged such that cement may be supplied to a space surrounding
10 and/or underlying the component in use.

A further aspect of the invention provides a method of cementing a cup-shaped component of or for a prosthesis, in which cement is provided to a space surrounding and/or underlying the component via one or
15 more apertures in the component.

It is preferred that the tool for positioning a cup-shaped component of or for a prosthesis includes a mating part engageable with the component, with a means for releasably locking the component thereto. The
20 mating part preferably includes one or more cement delivery orifices, which in the preferred embodiments just discussed, communicate with the aperture(s) in the cup component, so that, in use, cement can be supplied, via the aperture(s) to the space beneath and/or
25 surrounding the cup-shaped component whilst it is locked to, and thereby correctly positioned by, the tool. Once the cement has set, the locking means can be released and the positioning tool removed, leaving the component in place.

30 A preferred form of locking means may comprise retractable locking elements carried by the mating part, which cooperate between the mating part and the cup component.

35 This aspect of the invention finds particular utility in cementing joint prosthesis, or anchoring means therefor, in sockets of ball and socket joints of the human or animal body, such as the acetabulum or

scapula of the human hip and shoulder joints using, for example, a joint prosthesis such as that described in WO98/34567.

Consequently according to a still further aspect of
5 the present invention there is provided a joint prosthesis for replacing the socket of a ball and socket joint, the joint prosthesis having a generally cup-shaped anchoring means which has one or more apertures through which cement may be provided.

10 Thus, the anchoring means can be located in, for example, a natural socket, or an artificial bore in a socket, and cement can be then provided to the socket or bore through the aperture(s) in the anchoring means.

The anchoring means may be integral with the joint
15 prosthesis and, if the joint prosthesis comprises, for example, an artificial socket, the aperture(s) may extend through the artificial socket as well as the anchoring means. However, this may mean that a replacement or natural ball rests in the socket over the
20 aperture(s) and this may cause undesirable wear or deterioration of the ball.

It is therefore preferable that where the joint prosthesis is a socket, the aperture(s) are located at a location in the socket that supports the least load from
25 a corresponding ball in use. Thus, the aperture(s) are often located close to the rim of the socket and, as a ball that rests in the socket in use exerts most of its load through the base or centre of the socket, the pressure on the socket over the aperture(s) is reduced
30 and consequently wear and deterioration of the joint prosthesis is reduced.

Alternatively, the anchoring means is detachably mounted to the articulation component of the prosthesis and comprises further means for mounting or receiving
35 such component. For example, the articulation component may be an artificial socket and the receiving means may be a cup for receiving the artificial socket. Thus, the

cement aperture(s) of the anchoring means need not extend into the articulation component since this can be mounted in place after the anchoring means has been cemented in position. The articulation component may be
5 mounted to the anchoring means of the prosthesis by a tapering fit or by corresponding internal and external screw threads on the articulation component and the anchoring means.

The component of or for a prosthesis according to
10 any of the above aspects of the invention may be provided with one or more protrusions which engage the bone and which help maintain the desired position during cement delivery. This is additional to the positioning function achieved by the preferred tool of the invention
15 discussed above.

The seal provided in accordance with the above aspects may take any convenient form suitable for confining the cement in the space surrounding and/or underlying the prosthetic component. In a preferred
20 form, the seal may be of a generally annular or doughnut shape extending around the cement delivery tool such that the seal cooperates in use with the bone surrounding the site for the prosthesis. Cement may then be forced under pressure through the tool into the
25 space adjacent the prosthesis component and confined by the seal, preferably via one or more apertures in the component as discussed.

The seal may be an annular rubber or plastics ring, an umbrella type device or an iris or diaphragm
30 arrangement. However, in a preferred embodiment the seal comprises an inflatable balloon. This has the advantage of providing an improved sealing action against the bone, and may also provide enhanced pressurisation of the cement when inflated. In a
35 preferred apparatus and method, particularly applicable to a minimally invasive technique such as described in WO98/34567, the balloon is deflated and confined in

close proximity to or within the outer periphery of an elongate part of the tool when the tool is initially manipulated to position the prosthetic component in the body. This enables the elongate, preferably tubular, part of the tool provided with the seal to be conveniently inserted through an aperture in a bone, for example, or into or through another confined body space. Once the prosthetic component is correctly positioned, and preferably whilst still attached to the tool, the seal is inflated, for example by a suitable medium, such as saline, via a further conduit in the tool, to provide a seal against the surrounding tissue. Cement may then be forced into the space confined by the seal in a manner as described above.

In one embodiment, the deflated balloon is radially confined whilst the tool is being manipulated in the body. This may be achieved, for example, by retaining means such as an expandable mesh or umbrella device. However, in a preferred embodiment the retaining means comprises a plurality of pins which are initially fixed and extend approximately parallel to the axis of the tool, over the seal. The pins are releasable at their distal ends, and are pivotal in relation to the tool at their proximal ends so that they can be pushed outwardly when the seal is inflated into its sealing condition. Preferably, the retaining means or the pins also function to provide additional support behind the seal when it has been fully inflated.

This, in itself, is a new departure from the prior art and according to a still further aspect of the invention there is therefore provided a delivery device for delivering fluid to a cavity in a bone, the device comprising an elongate supply means having a generally ring or doughnut shaped seal which is carried within the radial dimensions of the supply means as the supply means is inserted, in use, through an orifice into a position for delivering fluid and is expandable outside

- 11 -

the radial dimensions of the supply means to seal the cavity whilst fluid is supplied in use from the supply means to the cavity.

One problem that may occur with inflatable balloon type seals is that, as significant expansion of the balloon may be required to expand the balloon from within the radial confines of a slender tool to a sufficient radius to seal a large cavity in a bone, the material from which the balloon is made may be under significant tension at full radial expansion of the balloon. This, in turn, may make the balloon vulnerable to puncture by, e.g., sharp bone fragments or edges or the tool itself. Similarly, the material may rupture due to inherent weaknesses or expansion beyond the material's inherent elastic limit.

Thus, in a particularly preferred embodiment of the invention the balloon has a relaxed diameter larger than the diameter of the tool and retaining means are provided for retaining the excess balloon material within the diameter of the tool or cement delivery device.

The use of retaining means is, in itself, considered to be a new advantageous departure from the prior art and, according to a further aspect of the present invention, there is provided a tool for sealing a cavity within a human or animal body, the tool comprising an elongate housing and annular seal for sealing the cavity, the seal being confined within the radial dimensions of the elongate housing for insertion of the tool into the human or animal body and expandable beyond the radial dimensions of the elongate housing to seal the cavity.

Preferably, the seal is a balloon. In this case it is preferable that the means for retaining the seal within the radial dimensions of the tool or housing comprises means for extending the balloon along the length of the housing. Thus, in a retracted position,

- 12 -

the balloon extends along the length of the housing, and, in its extended position, the balloon extends along the shorter length of the housing such that it bulges outwardly. This reduces the degree to which the balloon must be inflated to achieve a given radial expansion.

It is preferred that the balloon is made of latex. Likewise, it is also preferred that the balloon has a thickness of between 0.6 and 1 millimetre as this provides sufficient strength and resiliency for sealing cavities in bones.

In addition, the device may preferably, though not essentially, comprise means for detachably mounting, at its distal end, a component, such as a component of a prosthesis, to be secured in a cavity in a bone. This assists in initial positioning of the component, as in earlier aspects of the invention.

In this embodiment, cement can be applied to the cavity in a conventional manner and the tool, can be used to carry the component and position it in the cavity through a small aperture incision or bore, i.e. using minimally invasive surgical techniques. The seal may then be expanded to seal the cavity and/or pressurise cement by which the component is to be fixed into the cavity as appropriate. Likewise, the seal can be retracted to remove the tool through the aperture when the cement has set.

In particular, the component may be releasably attached to the tool as desired. However, in a particularly preferred embodiment the component is attached to the tool by suction. Thus, the tool may be provided with a head arranged to cooperate with the component and provided with a seal for providing an air-tight seal between the head and the component a passage through which the pressure within the space defined by the seal, the head and the component can be reduced to hold the component on the head of the tool. The means for providing a seal may be an 'O'-ring seal, and an

- 13 -

external surface of the head may co-operate with an inside surface of a cap-shaped component to bound the defined space.

5 The aspect of the invention is again considered to be particularly advantageous in its own right, and to be a departure from the prior art.

10 Thus, according to a further aspect of the invention there is provided a tool for positioning a component in a human or animal body, the tool comprising an elongate body having a head with a surface arranged to cooperate a surface of the component; a seal for sealing a perimeter of the cooperating surfaces; and a passage for withdrawing air from the space defined by the sealed surfaces so as to releasably hold the
15 component on the head of the tool.

20 Thus, a component may be attached to the tool by withdrawing air through the passage and, when the component has been positioned correctly in the human or animal body it can be released by releasing the vacuum in the passage. This has the particular advantage in surgical procedures of providing for releasable mounting of a component on a positioning tool without requiring any moving parts within the human or animal body during the procedure. The possibility of malfunction is
25 reduced as there are no moving parts that can become blocked or stuck and prevent release of the component.

30 According to the present invention there is also provided a cement delivery device for a prosthesis component, comprising cement supply means and a generally ring or doughnut shaped balloon which is carried by a part through which cement for cementing the component in place is supplied in use.

35 Certain of the above aspects of the invention may also have utility in cementing components, for example anchoring components of joint prostheses, such as elongate pins which are fitted in an elongate artificial bore or natural canal in a bone. For example, femoral

components of hip prostheses are generally located in the medullary canal of a femur. Alternatively, the femoral component may be fitted in an artificial extra-medullary bore, for example as described in WO98/34567.

5 Cement is generally provided from an accessible end of the bore or canal and the anchoring means is then positioned in the bore or canal. However, it is difficult to ensure that cement is provided along the entire length of the bore or canal as it is easy for air
10 or fluid pockets to develop.

The cement delivery means may therefore comprise plural elongate tubes which can extend into a bore or channel in which the component is located and simultaneously provide cement at different radial
15 locations around the component.

This, again, represents a new departure from the prior art, and viewed from a still further aspect of the present invention there is provided an apparatus for delivering cement around a component located in a
20 recess, bore or canal in a bone, the apparatus comprising plural nozzles which can simultaneously provide cement at different circumferential locations around the component.

Thus, cement is provided in a bone recess, bore or
25 canal at more than one radial location and there is less chance of air or fluid pockets developing in the cement.

The nozzles are preferably in the form of elongate tubes which can extend, in use, into a bone cavity such as an elongate bore or canal.

30 According to a further aspect of the present invention there is provided a method of delivering cement around a component located in a recess, bore or canal of a bone, the method comprising providing cement through one or more elongate tubes and retracting the
35 tube(s) from the recess, bore or canal as the cement is delivered.

Preferably the method further comprises moving the

tube(s) circumferentially around the prosthesis as the cement is delivered. This further enhances the provision of a homogeneous cement mantle and the chance of air or fluid pockets developing in the cement as it is delivered.

In a preferred embodiment of either of the above aspects, the tube or tubes is/are flexible, so that they can more easily be inserted into and withdrawn from an elongate bore or canal in a bone in use.

In a particularly preferred embodiment, two or more ideally four tubes are provided. This is particularly suitable for the risk of high viscosity cement as the tubes can be narrow in cross-section allowing restricted spaces to be assessed whilst providing plural outlet points such that a homogeneous cement mantle can be achieved. In another particularly preferred embodiment, one or more tubes of circumferentially elongate cross-sections are provided. For example, two tubes of horse shoe cross-section may be provided. Such an arrangement is suitable for higher viscosity cements, which require a larger overall cross-section of tubing for successful delivery, whilst still allowing delivery, a circumferentially confined region, such as that around a pin in an elongate bore to be accessed.

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side view of a cement delivery device according to the present invention;

Figure 2 is partial cross sectional view of the cement delivery device of Figure 1 along the line I-I in figure 1;

Figure 3 is view similar to that in Figure 1 of a second cement delivery device according to the invention in use;

Figure 4 is a sectional side view of first example of a component of a joint prosthesis cemented in an

acetabulum;

Figure 5 is a sectional side view of second example of a component of a joint prosthesis cemented in an acetabulum;

5 Figure 6 is a sectional side view of third example of a component of a joint prosthesis cemented in an acetabulum;

10 Figure 7 is a sectional side view of fourth example of a component of a joint prosthesis cemented in an acetabulum;

Figure 8 is a sectional side view of a third embodiment of a cement delivery device according to the invention;

15 Figure 9 is a sectional side view of a fifth example of a component of a joint prosthesis which has been cemented in an acetabulum using the cement delivery device shown in Figure 8;

20 Figure 10 is a sectional side view of a head of a tool for positioning a component of a joint prosthesis according to the invention with its seal retracted;

Figure 11 is a sectional side view of the head of the tool of Figure 10 with its seal extended;

25 Figure 12 is a sectional side view of a fourth embodiment of a cement delivery device according to the invention in a femur;

Figures 13a and 13b are views of caps for use with the cement delivery device shown in Figure 12;

Figure 14 is a view of the cement delivery device of Figure 12 in use;

30 Figure 15 is a sectional side view of a fourth embodiment of a cement delivery device according to the invention in a femur; and

Figure 16 is a view of the delivery device of Figure 15 in use.

35 Referring to Figure 1, a cement delivery device 1, having a generally elongate construction, is provided. This cement delivery device 1 is particularly suited to

applications in which cement is to be delivered to a location through a restricted orifice, an aperture in body tissue, or a narrow bore in a bone such as described, for example, in WO98/34567 (i.e. minimally
5 invasive surgery). However, the cement delivery device may be used, with or without modification, for other purposes. In particular, use of the device in other applications such as conventional hip replacement procedures may be realised with a construction which is
10 not elongate.

The cement delivery device 1 has main body 2 with a placement head 3 mounted at a distal end of the body 2 such that it can slide in the direction of the longitudinal axis of the body 2 (and cement delivery
15 device 1) toward and away from the body 2. More specifically, the head 3 is mounted on a tube 4 which fits inside a tube 5 in the body 2 having an inner diameter at its distal end the same or slightly larger than the outer diameter of the tube 4. The tubes 4 and
20 5 form part of a cement delivery passage 16 along the longitudinal central axis of the cement delivery device 1.

Between the head 3 and the body 2, an annular seal 6 extends around the tube 4 of the head 3. When it is
25 required to use the cement delivery device in minimally invasive surgery the seal 6 is collapsable and expandable. This facilitates insertion of the device through a narrow opening or bore and subsequent expansion of the seal to suitable dimensions when the
30 device has been inserted. In this example the seal 6 comprises an annular or doughnut shaped balloon 6 extending around the tube 4. The balloon 6 is inflatable and to allow inflation and deflation the balloon 6 has an opening 7 connected to a passage 8 in
35 the body 2. The passage 8 extends from the balloon to an inlet opening 9 at a proximal end of the body 2 of the cement delivery device 1. The inlet opening 9 is

adapted to receive a connector of a fluid delivery apparatus, such as a syringe, containing saline or some other suitable medium for inflating the balloon 6.

In this example, the head 3 has a shape which
5 tapers away from the body 2 and is arranged to fit with a cup shaped component 10 of a joint prosthesis. However, the component 10 need not be a component of a joint prosthesis, but may equally well be any component for fitting in any cavity or bore (whether natural or
10 artificial) in a bone of a human or animal body, such as an anchoring means for a joint prosthesis or the head of a fracture nail.

The head 3 is provided with one or more retaining pins 11, each slidably disposed in a bore 12 in the head
15 3, for detachably retaining the component 10 on the head 3. In this example, each bore 12 extends between the cement delivery passage 16 in the head 3 and an outer tapering surface of the head 3. Each retaining pin 11 is slightly longer than the length of the bore 12 in
20 which it is arranged, such that it protrudes either from the tapering surface or into the hollow cavity, and its movement is restricted by a collar in the bore 12 such that it remains in the bore 12. The retaining pins 11 are each arranged to co-operate with an indent 70 in a
25 surface of the component 10 that faces the tapering surface of the head 3. In this example the indent 70 comprises an annular recess running around the surface of the component 10 for engaging all of the retaining pins 11, but smaller individual indents 70 may be
30 provided for each retaining pin 11 if preferred. An actuating tool (not shown) comprising a long shaft with a tapering head or cam surface can be inserted along the cement delivery passage 16 to force the retaining pins
35 11 outwards, with the component 10 in place on the head, such that the retaining pins 11 protrude from the bores 12 so as to engage the indents of the component 10 and retain the component 10 on the head 3.

At the other, proximal, end of the body 2, there is an opening into the cement delivery passage 16. In Figure 1 a cement injecting apparatus 74 is shown inserted into the passage 16. The cement injecting apparatus 74 comprises an arrangement 75 for carrying and injecting cement and a tube or sleeve 73 which fits in the passage 16.

The distal end of the body 2 (proximal to the head 3) carries retaining means for retaining the balloon 6 within the radial dimensions of the body 2 and for supporting the balloon 6 when it is inflated. In this example, the retaining means comprises a plurality of pins 13 carried by the body 2 and spaced around its circumference. The pins 13 are pivotally connected to the body 2 by pivot means 71 such that they can pivot from a position parallel to the major axis of the body 2 outwardly through an angle A to a position in which they extend partially radially from the body 2, as shown in Figures 1 and 2. To prepare the apparatus for use, the head 3 is moved away from the body 2 and the pins 3 are positioned such that they are parallel to the major axis of the body 2 and retain the balloon 6 under them, within the diameter of the body 2. The head 3 is then moved back toward the body 2 such that the end of each pin 13 distal from its pivotal engagement with the body 2 engages a corresponding recess 14 on a surface of the head 3 facing the body 2. In this position, the pins 13 aid insertion of the cement delivery device 1 through an orifice or bore by confining the balloon 6.

After the device 1 has been manoeuvred into position for delivering cement, the head may be urged away from the body 2. In this example, this is achieved by pushing the sleeve 73 in the passage 16 toward the head 3. As the head 3 moves away from the body 2 the pins 13 disengage from the indent(s) 14 and may be urged outwards by the balloon 6 as it is inflated.

In their deployed condition, as shown in Figures 1

- 20 -

and 2, the pins 13 support the proximal surface of the seal or balloon 6 when it is inflated, as shown in Figure 3. This allows any force exerted along the direction of the major axis of the cement delivery device 1 toward the position of the component 10 or area of cementing to push the seal or balloon 6 as well as the head 3.

Refer now to Figure 3, a cement delivery device 1 similar to that shown in Figures 1 and 2 is shown in position for cementing a component 10 into a socket 18 of an acetabulum 15. This cement delivery device 1 has a head adapted to carry a component which is adapted to be located in pre-drilled holes 76 in a socket or cavity 18, as opposed to on the spike 77 of the component 10 shown in Figure 1. Also, in their deployed condition, the end of each pin 13 proximal to the body 2 rests against a stop 78 which limits the angle A through which the pins can pivot. The pins therefore securely support the inflated balloon 6.

In use, the cement delivery device 1 is inserted through a bore in a bone, such that the head 3 is proximal to a bore, recess or, in this example, a cavity 18 in which a component of a joint prosthesis is to be placed. This is particularly useful when placing the joint prostheses described in International Patent Application No. WO98/34567, which may be put into place through a bore in a femur. The cement delivery device 1 is used to manipulate the component 10 until it is in the correct position. This may be aided by using X-ray imaging to show the position of the component next to the bone. The manipulation may be carried out by a robotic or other computer-aided surgical technique. Marks may be provided or placed on the body 2 of the cement delivery device 1 to help to show the position of the component 10 either visually or in X-ray imaging. For example, the length of the body 2 may be marked with indications along its length which may, for example, protrude from the diameter of the body 2 to show up in

X-ray imaging. Similarly, the devices may be fitted with temperature and/or pressure transducers to provide feedback to an automated system. Still further, the cement delivery device 1 may have a cooling system, for example comprising tubes for carrying coolant around the body 2, to regulate the temperature of the cement as it is injected into a cavity or bore and sets.

Once the component 10 has been correctly located in the bone 15, such as an acetabulum 15, as shown in Figure 3, the balloon 6 is inflated by passing a suitable medium, such as saline, through inlet opening 9 and along the passage 8. The balloon 6 expands to form a seal with tissue in the socket of the acetabulum 15. The balloon 6 may seal the cavity by taking any suitable shape, but the seal shown in this example is particularly adapted for sealing a socket or cup shaped cavity (such as the acetabulum 15 shown in Figure 3) as it presses radially outward against a ring of tissue or bone rather than resting on the rim of bone surrounding the socket. In this position, the pins 13 support the balloon 6 such that it does not pop out of the socket, and such that it exerts some pressure on the cavity 17 formed between the balloon 6 and the socket 18. A force toward the cavity 18 is maintained on the device by a robot arm, automated clamp type device or manually by a surgeon, to keep the seal in place and hold the component still.

With the component 10 correctly positioned and the seal properly positioned, or balloon 6 properly inflated, to form a suitable seal, cement is injected using the cement injecting apparatus 74 along the passage 16 or, more specifically, through the sleeve 73 in the passage 16. The cement passes along the sleeve 73 and through one or more openings in the component 10 into the cavity 17 between the balloon and the acetabular socket 18. The cement can be provided at a pressure higher than that of fluids within the body such

that any fluid in the cavity 17 is driven out of the cavity 17 and the cavity 17 is filled with cement.

The cement delivery device 1 and balloon 6 remain in position until the cement has set. The fluid in the balloon 6 is then removed through the inlet opening 9 to deflate the balloon 6 and allow the pins 13 to collapse inwardly. The cement delivery device 1 can then be removed from the bore or orifice through which it was inserted.

Various components may be cemented using the cement delivery device described above. Referring to Figure 4, in one embodiment, a socket component 19 of a joint prosthesis is cemented in place using the cement delivery device 1. This component 19 has two apertures 20 through which cement may be passed to cement the component 19 in place. Additionally, in the embodiment shown the acetabular socket 17 has been prepared by drilling a number of holes 72 in its surface to aid location of the cement and strengthen the bond between the cement and the bone.

The apertures 20 through which cement is injected are located close to the rim of the socket 21 of the component 19. Thus, when a ball is placed in the socket 21 to complete the joint prosthesis, the major forces exerted on the socket are not exerted in the area of the apertures 20. This reduces any erosion or wear that may be caused by the ball rotating over cement exposed in the apertures 20.

Referring to Figure 5, a third embodiment of component 10 is shown. This two part component 22 comprises an anchoring part or anchoring means 24 and an articulation part 23. The anchoring part 24 is cemented in place in a similar manner to the components 10 and 19 of the above described embodiments, i.e. it is put in position using a cement delivery device 1, a seal is provided and cement is injected. However, the anchoring part 24 does not have a socket 21, but instead has a

- 23 -

tape recess 25 for receiving a portion 26 of the articulation part 23. Thus, cement can be inserted through apertures (not shown) in the anchoring part 24, and the articulation part 23 can be located in the anchoring part 24 after the anchoring part 24 has been cemented in place. In this example, the portion 26 of the articulation part 23 fits in the recess 25 of the anchoring part 24 by a friction fit. The articulation part 23 and the component 22 generally, provide a smooth socket 27 which has no apertures in its surface. This further reduces wear of a ball and socket joint.

Referring to Figure 6, in a fourth embodiment a two-part component 22 of a joint prosthesis is again provided. However, in this example an anchoring part 28 is cemented in place and articulation part 29 component having a socket 30 is joined to the anchoring part 28 by means of a screw thread, rather than the friction fit of tapering surfaces.

Referring to Figure 7, a fifth embodiment of a component of a joint prosthesis comprises a pin 31 which may be inserted into an artificial bore 32 in an acetabulum 15. In this example, the pin 31 comprises two parts, a first outer sleeve 33 having orifices 34 through which cement can be inserted, and a second inner sleeve 35 which fits inside the outer sleeve 33 to provide a stable support. The outer sleeve 33 is fitted in a similar manner to the anchoring parts of the above described embodiment and the inner sleeve 35 in position later.

Referring to Figures 8 and 9, a sixth embodiment of a component for a joint prosthesis comprises a cup-shaped component 40. It can be appreciated that a component 40 having dimensions similar to that shown in the Figure cannot be inserted through a narrow bore or orifice, and it is intended that this is inserted in an acetabulum using a conventional joint replacement technique. However, a cement delivery device 1 in

accordance with the invention may still be utilised, although it is preferred that the cement delivery device then comprises a head 41 (as shown in Figure 9) having a larger diameter than the head 3 of previous embodiments.

5 The head 41 has an annular seal 43 which fits over the bone or tissue surrounding the socket 17 of the acetabulum 15 to provide a seal which is supported by pressure exerted through the cement delivery device 1 towards the socket 17, rather than radially outwards
10 around the inside of the rim of the socket 17 as in the previous embodiments described above. The annular seal 43 need not be inflatable, and may comprise a sealed annular 'O'-ring.

 The head 41 has two or more passages 42 for
15 delivering cement through apertures 78 at the periphery of the component 40. Thus cement is injected around the periphery of the socket 17 and a more homogeneous cement mantle may be provided. A further annular seal 78 is provided inward of the passages 42 to prevent cement
20 from entering the artificial socket 79. Pins 80 on the head 41 engage recesses 81 to hold the component 40 during positioning and cement delivery.

 Referring to Figures 10 and 11, a tool 100 for positioning a component of a joint prosthesis, which can
25 be used in a slightly more conventional method of fixing components to bones, has a number of features in common with the cement delivery devices described above.

 The tool 100 comprises an elongate housing 101 which, in this example, is suitable for positioning a
30 component of a prosthesis by inserting it through a bore in a bone such as described in WO98/34567. At the distal end of the housing 101, a head 102 is provided for carrying the component. The head comprises a domed or conical surface adapted to mate with a surface of the
35 component (in this case a socket of a ball and socket joint to be mounted in an acetabulum).

 Passing through the central axis of the dome or

- 25 -

cone of the head is a passage 103 connected to a main passage 104 passing along the length of the housing 101 of the tool 100. Outwardly of the opening of the passage 103 in the head 102 is an 'O'-ring seal 105
5 adapted to form a seal with the component when it is mounted on the head 103. In this example, the 'O'-ring seal is an annulus around the base of the domed or conical surface of the head 103.

Rearwardly or behind the head 103, the tool 100
10 carries a balloon 106. The balloon 106 comprises a tube of suitably pliable and elastic material such as rubber or latex. Typically, a thickness of 0.6 millimetres to 1 millimetre is suitable.

The balloon 106 extends from a fixed collar 107
15 just behind the head 102 to a movable collar 108 provided within the housing 101. One end of the balloon is sandwiched between a base 109 and retaining portion 110 of the fixed collar 107 and two 'O'-rings seals are provided between the balloon and the retaining portion
20 110 to provide a water-tight seal around the entire circumference of that end of the balloon.

The movable collar 108 similarly comprises a base 112 and a retaining cover 113, this time sandwiching the other end of the balloon 106. Again, 'O'-ring seals are
25 provided between the balloon 106 and the retaining cover 113 to ensure a water-tight seal around the entire circumference of that end of the balloon 106. The base 112 and retaining cover 113 of the movable collar 108 are fixed to an accuator, which in this example
30 comprises a tube 115 disposed within the housing 101. In this example, the base 112 and retaining cover 113 of the movable collar 108 are attached to the tube 115 by sandwiching the tube 115. The whole assembly of the tube 115, collar 108 and balloon 106 is slidable within
35 the housing 101, although the distal end of the balloon, behind the head 102 is fixed. Thus, the balloon 106 extends between two cars or collars 107, 108, one of

which is movable to decrease the length of the balloon 106 and accordingly increase its diameter.

In this example, around 40 to 50 millimetres of balloon material extends between the collar just behind the head 102 to the movable collars 107, 108. However, the housing extends forward of the movable collar 108 in its retracted position shown in Figure 10, and only a small gap, in this example 20 millimetres, is provided between the head 102 and the housing 101 at which the balloon is exposed.

A fluid passage 105 extends along the length of the housing 101 into the space defined inwardly of the balloon 106. Fluid, such as saline, can be injected into the space to inflate the balloon 106. The movable collar 108 slides forward on inflation to increase the diameter of the balloon. Thus, the balloon 106 need not be as elastic as the balloon as the embodiments described above, as the balloon 106 is not required to inflate to the same extent.

In use, cement is first applied to the area to which a component for a prosthesis is to be attached. The tool 100 is prepared by placing the component (such as that illustrated in Figure 4 although without the apertures 20 through which cement is injected) on the head 102 of the tool 100. A seal is formed between the rim of the component and the 'O'-ring 105 and air is withdrawn through the passages 103 and 104 such that the component is held on the head 102 by vacuum.

The tool 100, carrying the component is then inserted by the incision or bore through which access is gained to the area or cavity in which the component is to be fixed, such that the component is brought into a position close to the position in which it is to be fixed. The balloon 106 is in the retracted position shown in Figure 10 during insertion such that the balloon is protected and the tool 100 can be easily inserted through the incision or bore.

Once the tool 100 and component are in position close to the intended position in which the component is to be fixed, the collar 108 is moved towards the distal end of the tool 100 and saline is injected into the
5 space defined by the balloon 106 through the passage 115 to inflate the balloon 106. The balloon 106 is thus inflated as shown in Figure 11 without the material from which the balloon is made being stretched to a large extent. This reduces the possibility of the balloon 106
10 being punctured or ruptured due to contact with bone or body tissues, as the balloon 106 does not stretch to a large extent.

The tool 100 is then pushed forward such that the component is brought forward into the final position in
15 which the component is to be fixed and the balloon 106 seals the cavity or area in which cement has been provided and pressurises the cement. This ensures that any bodily fluids are expelled from the area of the cement and that a homogenous cement mantel is produced.

20 When the cement has set, the vacuum or reduced pressure in the passages 103 and 104 is released such that the component is no longer held on the head 102 and the tool 100 is released. Likewise, saline is withdrawn from the balloon 106 of the movable collar 108 is moved
25 away from the head such that the balloon 106 is retracted. The tool 100 may then be withdrawn through the bore or incision through which it was inserted.

Referring to Figures 12, 13a and 13b, in a further embodiment the cement delivery device has a plurality of
30 tubes 50 which extend from the end of the cement delivery device into a cavity in which cement is to be injected. In the example illustrated in Figures 12, 13a and 13b, a component 52 is cemented in an extra-medullary bore 54 in a femur 51. The component 52 has a
35 seal 53 at its medial, wider end, which seals one end of the bore 54. A cap 55 or 57, as shown in Figures 13a or 13b, is fitted over the other end of the bore 54. This

engages the distal end of the component 52 to hold it along the central axis B of the bore 54. In this example, the cap 55 or 57 also seals the end of the bore over which it fits. The cap 55 has a plurality of
5 apertures 56 (shown in Figures 13a and 13b) through which the cement delivery tubes 50 can be inserted and, in use, the delivery tubes 50 are inserted through the cap 55 or 57 as far as the seal 53.

As shown in Figure 14, as cement is injected
10 through the tubes 50 into the cavity 54, the tubes 50 are gradually withdrawn from the cavity. This results in a particularly homogeneous cement mantle which is stronger than those of the prior art.

Alternatively, the apertures 56 may be formed as slots
15 which extend circumferentially around the cap 55 or 57, or the cap 55 or 57 may be arranged to rotate. This enables the tubes 50 to be rotated circumferentially around the pin 52 as they are withdrawn (i.e. along generally helical paths) which also aids the provision
20 of a homogeneous cement mantle.

Referring now to Figure 15, the cement delivery device of the above embodiment can be adapted for use with a femoral component 63 which extends along the medullary canal of a femur 51. In this example, the
25 medullary canal 60 is plugged at its lower end with a seal 61, and the femoral component 63 is inserted in the bore 60. Referring to Figure 16, cement is delivered to the bore 62 in a way similar to that of the above embodiment, by withdrawing the tube 64 from the bore 62
30 as cement is injected. To aid provision of a homogeneous cement mantle, the tubes may be rotated around the circumference of the bore as they are withdrawn, although this is only possible where the shape of the prosthesis 63 or other component being
35 cemented in position allows.

In the embodiments shown in Figures 12 and 13a four flexible tubes 50, which are circular in cross-section,

are provided. Such an arrangement is suitable for the application of low viscosity cement. In an alternative arrangement, larger diameter tubes 50 may be used for higher viscosity cements, which generally have quicker setting times and are generally advantageous as they can reduce the length of surgical procedures. In particular, two tubes 50 may be used each having a horse shoe cross-section. Such an arrangement uses a cap 57, as shown in Figure 13b, having two apertures comprising diametrically opposed horse shoe shaped slots. This arrangement is useful for the application of higher viscosity cement around a component, such as that shown in Figure 12 in a circumferentially confined space as it maximises the cross-sectional area of the cement delivery tubes for a given circumferential space.

It will be understood that the above described embodiments may be adapted or varied within the scope of the claimed invention. For example, the device 1 may not have means for placing a component and may instead be used fill joints or, if preferable, to place cement in a cavity or bore in a bone before a component is positioned, as the device still has the advantage of being able to cleanly and reliably deliver cement to a cavity or bore through a small aperture or bore. Likewise, the various corresponding features of each of the various embodiments are broadly interchangeable with one another.

CLAIMS

1. Apparatus for positioning and cementing a component of or for a prosthesis, the apparatus comprising means
5 for positioning the component in or adjacent a bone cavity, cement delivery means for providing cement under pressure to a cavity space next to the component whilst the component is in its desired position, and a seal carried by the cement delivery means and arranged to
10 confine the cement in such space until it has set.
2. The apparatus of claim 1, wherein the component is part of a joint prosthesis for mounting in a natural cavity of a joint.
- 15 3. The apparatus of claim 1 or claim 2, wherein the component is a cup component of an artificial hip prosthesis for mounting in the acetabular socket of a hip.
- 20 4. The apparatus of any one of claims 1 to 3, wherein the means for positioning the component in or adjacent a bone cavity comprises a tool provided with carrying means on which the component for the prosthesis is
25 releasably mounted.
5. An apparatus for positioning a component of or for a prosthesis, the apparatus comprising a tool having a distal end to which the component is releasably
30 mountable such that the component is fixed to the tool and can be carried and manipulated thereby, wherein the tool also has cement delivery means for cementing the component or in a cavity in a bone within the body whilst the component is still mounted to the tool and
35 positioned thereby.
6. The apparatus of claim 5, further comprising a seal

- 31 -

for confining the cavity in which the component is to be cemented.

- 5 7. The apparatus of any one of claims 4 to 6, wherein the tool includes an elongate, tubular housing, and the means for releasably mounting the component is provided at the distal end of the housing.
- 10 8. The apparatus of any one of claims 1 to 7, further comprising an endoscope for providing the surgeon with an image of the site of the component to assist guidance and location.
- 15 9. The apparatus of any one of claims 1 to 8, further comprising a temperature and/or pressure transducer to either aid automation or to assist a surgeon in noting pressure being applied or the temperature of the cement as it sets.
- 20 10. The apparatus of any one of claims 1 to 4 or 6 to 9, further comprising means for forcing cement under pressure, through a tube, and into the space defined by the cavity and the component and confined by the seal.
- 25 11. The apparatus of any one of claims 1 to 10, wherein the cement is supplied via one or more apertures in the component itself.
- 30 12. A cup-shaped component of or for a prosthesis, which component is intended to be cemented in position, and which includes one or more apertures which are arranged such that cement may be supplied to a space surrounding and/or underlying the component in use.
- 35 13. The apparatus of any one of claims 1 to 11, further comprising a mating part engageable with the component and locking means for releasably locking the component

thereto.

14. The apparatus of claim 13 wherein the locking means
comprise retractable locking elements carried by the
5 mating part that cooperate between the mating part and
the cup component.

15. The apparatus of claim 13, wherein the locking
means comprises means for attaching the component to the
10 mating part tool by suction.

16. The apparatus of claim 15, wherein the mating part
comprises a head arranged to cooperate with the
component, the head having a seal for providing an air-
15 tight seal between the head and the component and a
passage through which the pressure within the space
defined by the seal, the head and the component can be
reduced to lock the component on the head of the tool.

20 17. The apparatus of claim 16, wherein the means for
providing a seal is an 'O'-ring seal.

18. The apparatus of claim 16 or claim 17, wherein an
external surface of the head co-operates with an inside
25 surface of a cup-shaped component to bound the defined
space.

19. A apparatus for positioning a component in a human
or animal body, the apparatus comprising an elongate
30 body having a head with a surface arranged to cooperate
a surface of the component; a seal for sealing a
perimeter of the cooperating surfaces; and a passage for
withdrawing air from the space defined by the sealed
surfaces so as to releasably hold the component on the
35 head of the tool.

20. The apparatus of any one of claims 1 to 11 or 13 to

19, including one or more cement delivery orifices which communicate with aperture(s) in the component, so that, in use, cement can be supplied, via the aperture(s) to the space beneath and/or surrounding the component
5 whilst the component is locked to, and thereby correctly positioned by, the tool.

21. A joint prosthesis for replacing the socket of a ball and socket joint, the joint prosthesis having a
10 generally cup-shaped anchoring means which has one or more apertures through which cement may be provided.

22. The joint prosthesis of claim 21 or claim 22, wherein the joint prosthesis is a socket and an
15 aperture(s) are located close to the rim of the socket.

23. The joint prosthesis of claim 21 or claim 22, wherein the anchoring means is detachably mounted to an articulation component of the prosthesis and comprises
20 further means for mounting or receiving such component.

24. The joint prosthesis of claim 23, wherein the articulation component is mounted to the anchoring means by a tapering fit.
25

25. The joint prosthesis of claim 23, wherein the articulation component is mounted to the anchoring means by corresponding internal and external screw threads on the articulation component and the anchoring means.
30

26. The joint prosthesis of any one of claims 21 to 25, further comprising one or more protrusions which engage the bone and which help maintain the desired position during cement delivery.
35

27. The apparatus of any one of claims 1 to 4, 6 to 11 or 13 to 18, wherein the seal is a generally annular or

doughnut shape extending around the cement delivery means such that the seal cooperates in use with the bone surrounding the site for the component.

5 28. The apparatus of claim 27, wherein the seal comprises an inflatable balloon.

29. The apparatus of claim 28, further comprising retaining means for radially confining the deflated
10 balloon whilst the tool is being manipulated in the body.

30. The apparatus of claim 29, wherein the retaining means comprises a plurality of pins which are initially
15 fixed and extend approximately parallel to the axis of the tool, over the balloon.

31. The apparatus of claim 30, wherein the pins are releasable at their distal ends, and are pivotal in
20 relation to the tool at their proximal ends so that they can be pushed outwardly when the balloon is inflated into its sealing condition.

32. The apparatus of claim 30 or claim 31, wherein the
25 pins provide additional support behind the seal when it has been fully inflated.

33. An apparatus for delivering fluid to a cavity in a bone, the apparatus comprising an elongate supply means
30 having a generally ring or doughnut shaped seal which is carried within the radial dimensions of the supply means as the supply means is inserted, in use, through an orifice into a position for delivering fluid and is expandable outside the radial dimensions of the supply
35 means to seal the cavity whilst fluid is supplied in use from the supply means to the cavity.

34. An apparatus for sealing a cavity within a human or animal body, the apparatus comprising an elongate housing and annular seal for sealing the cavity, the seal being confined within the radial dimensions of the elongate housing for insertion of the tool into the human or animal body and expandable beyond the radial dimensions of the elongate housing to seal the cavity.

35. The apparatus of any one of claims 29 to 34, wherein the seal is a balloon and the retaining means comprises means for extending the balloon along the length of the cement delivery means or housing.

36. The apparatus of any one of claims 29 to 35, wherein the seal is a balloon having a natural relaxed diameter larger than the diameter of the tool and said retaining means is effective to retain the excess balloon material within the diameter of the tool or cement delivery device during insertion.

37. The tool of any one of claims 28 to 36, wherein the balloon is made of latex.

38. The tool of claim 37, wherein the balloon has a thickness of between 0.6 mm and 1 mm.

39. An apparatus for cementing a prosthetic component in place, comprising cement delivery means and a generally ring or doughnut shaped balloon which is carried by a part through which cement for cementing the component in place is supplied in use.

40. The apparatus of any one of claims 1 to 20 or 27 to 33, wherein the cement delivery means comprises plural elongate tubes which can extend into a bore or channel in which the component is located and simultaneously provide cement at different radial locations around the

- 36 -

component.

5 41. An apparatus for delivering cement around a component located in a recess, bore or canal in a bone, the apparatus comprising plural nozzles which can simultaneously provide cement at different circumferential locations around the component.

10 42. The apparatus of claim 41, wherein the nozzles are preferably in the form of elongate tubes which can extend, in use, into a bone cavity such as an elongate extend, in use, into a bone cavity which as an elongate bore or canal.

15 43. The apparatus of claim 41 or 42, wherein the tubes are flexible.

20 44. The apparatus of claim 41, 42 or 43, having four tubes.

45. The apparatus of claim 41, 42 or 43, having one or more tubes of circumferentially elongate cross-sections.

25 46. A method of cementing a component of or for a prosthesis into or adjacent a bone cavity, comprising locating the component in a desired position, providing a seal, and providing cement under pressure into a cavity space next to the component and confined by the seal.

30 47. The method of claim 46, wherein the provision of the seal comprises locating over the cavity a seal carried by the cement delivery means.

35 48. The method of claim 46 or claim 47, further comprising removing the seal when the cement has set.

- 37 -

49. The method of any of claims 46 to 48, further comprising pressurising the cement with the component in its intended final position.

5 50. The method of any one of claims 46 to 49, further comprising inserting and locating the component through an incision distal from the intended position of the component.

10 51. The method of claim 50, further comprising inserting and locating the component through a bore in a bone.

15 52. A method of cementing a cup-shaped component of or for a prosthesis, in which cement is provided to a space surrounding and/or underlying the component via one or more apertures in the component.

20 53. A method of delivering cement around a component located in a recess, bore or canal of a bone, the method comprising providing cement through one or more elongate tubes and retracting the tube(s) from the recess, bore or canal as the cement is delivered.

25 54. The method of claim 53, further comprising moving the tube(s) circumferentially around the prosthesis as the cement is delivered.

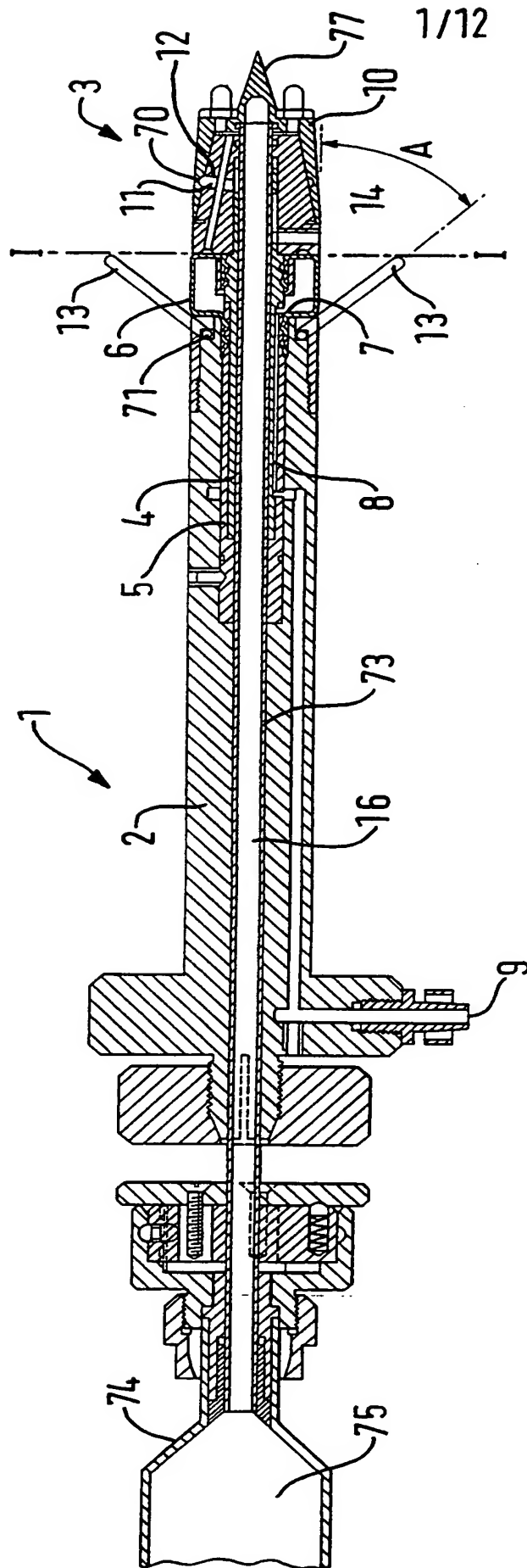


FIG. 1

2/12

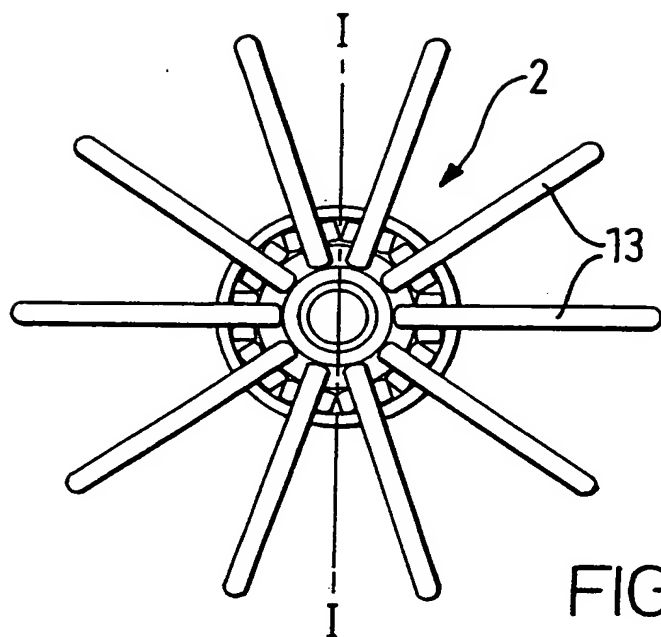


FIG. 2

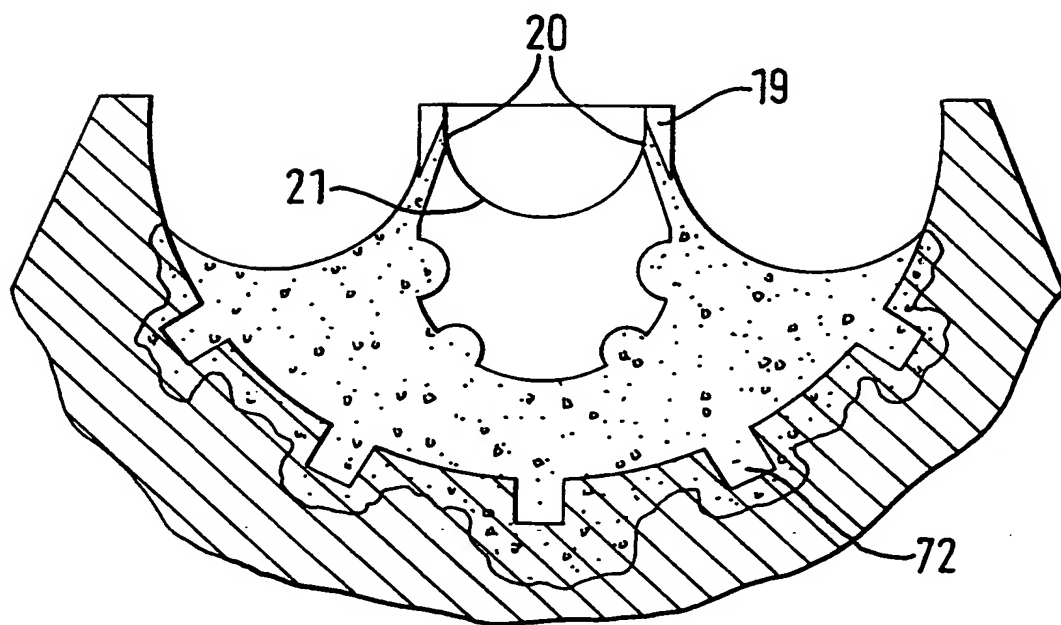


FIG. 4

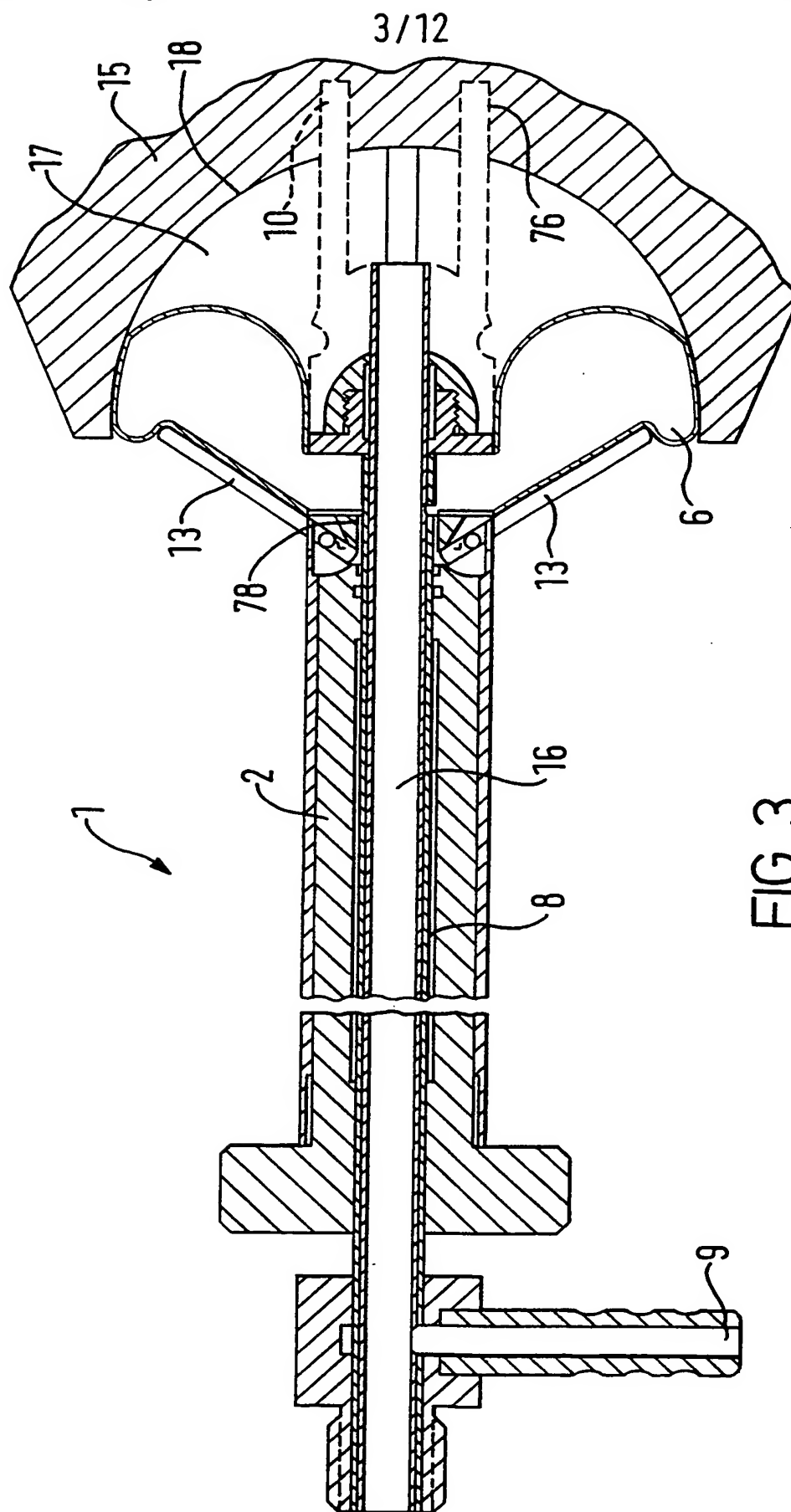


FIG. 3

4/12

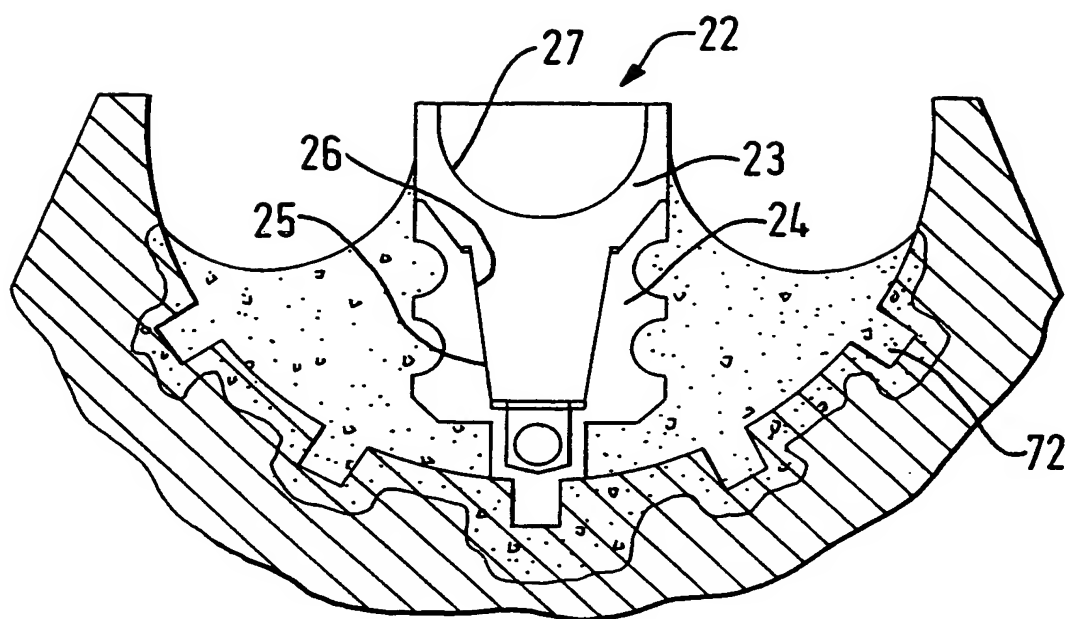


FIG. 5

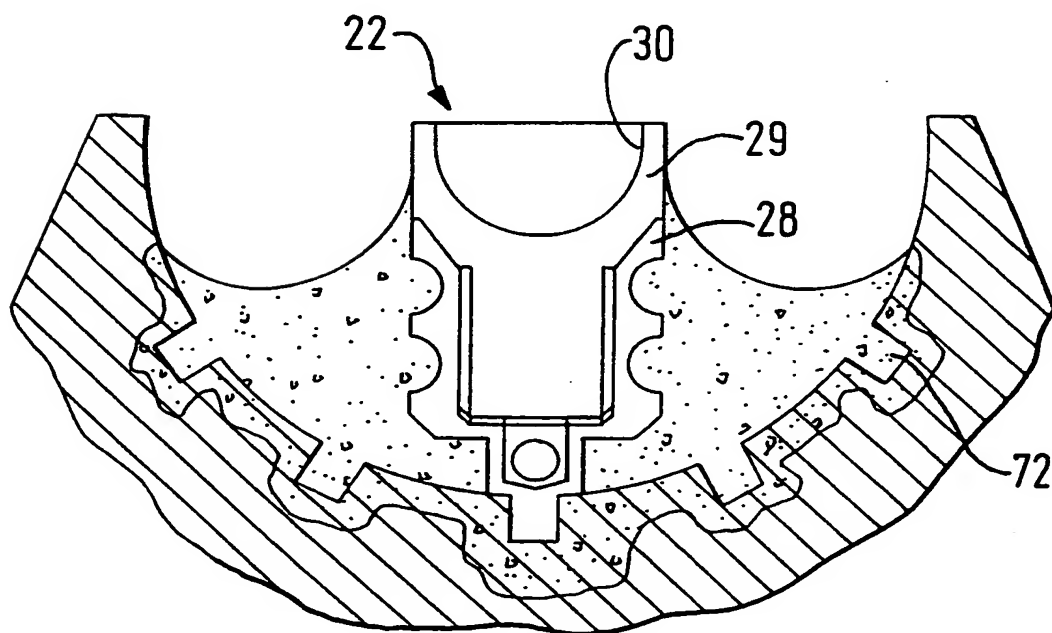


FIG. 6

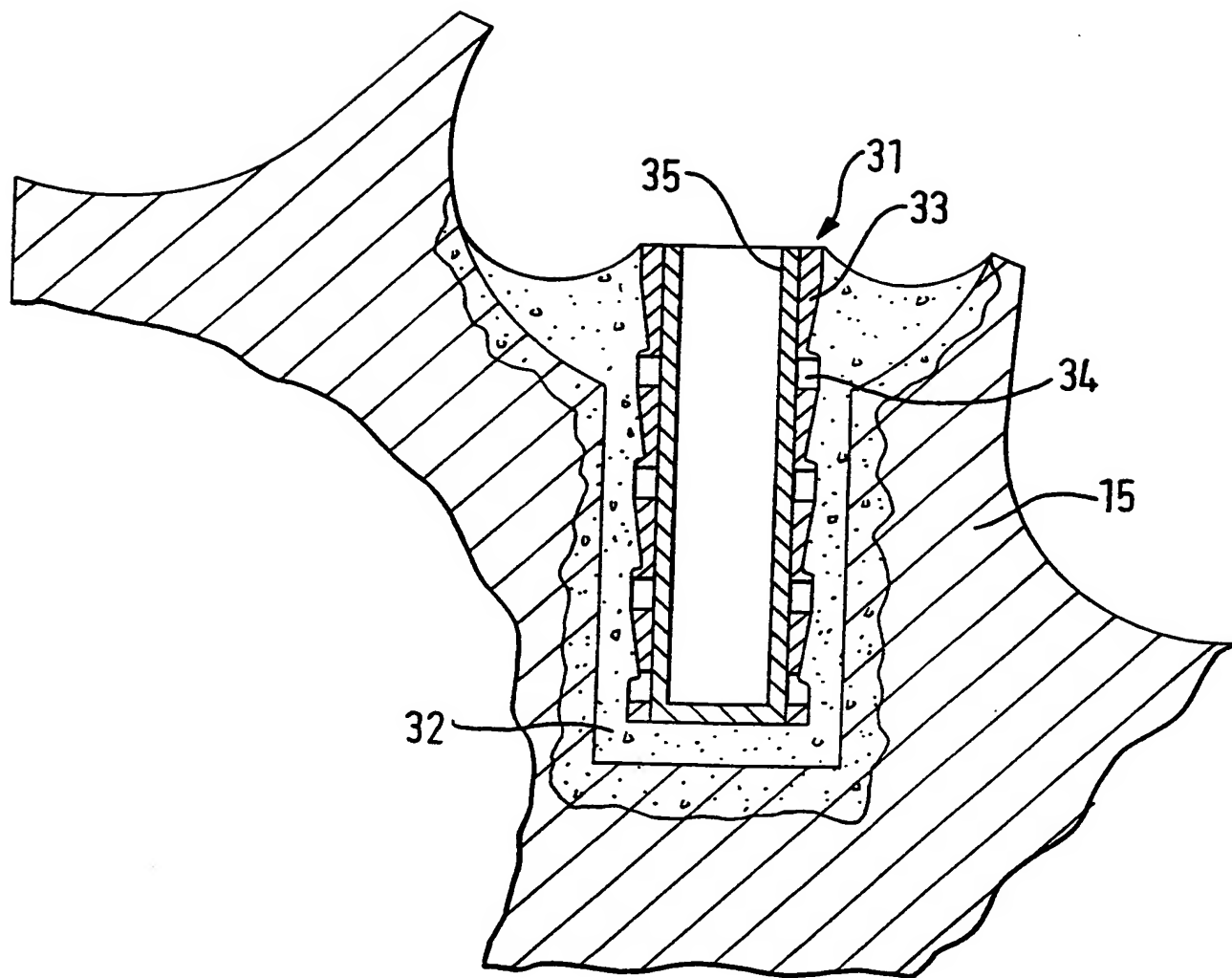


FIG. 7

6/12

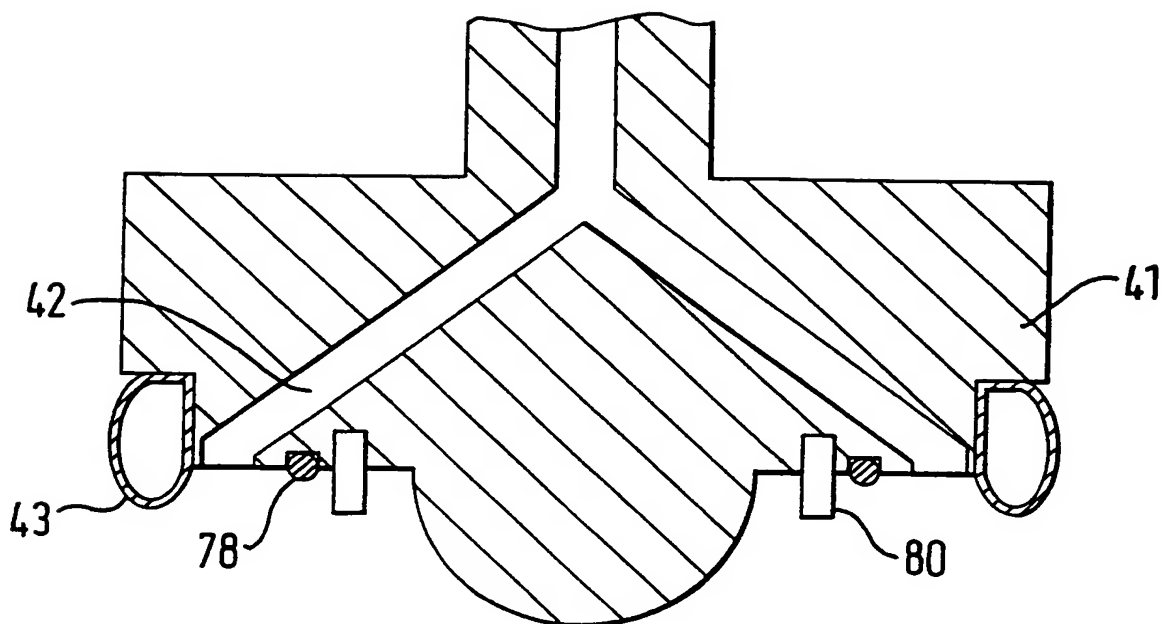


FIG. 8

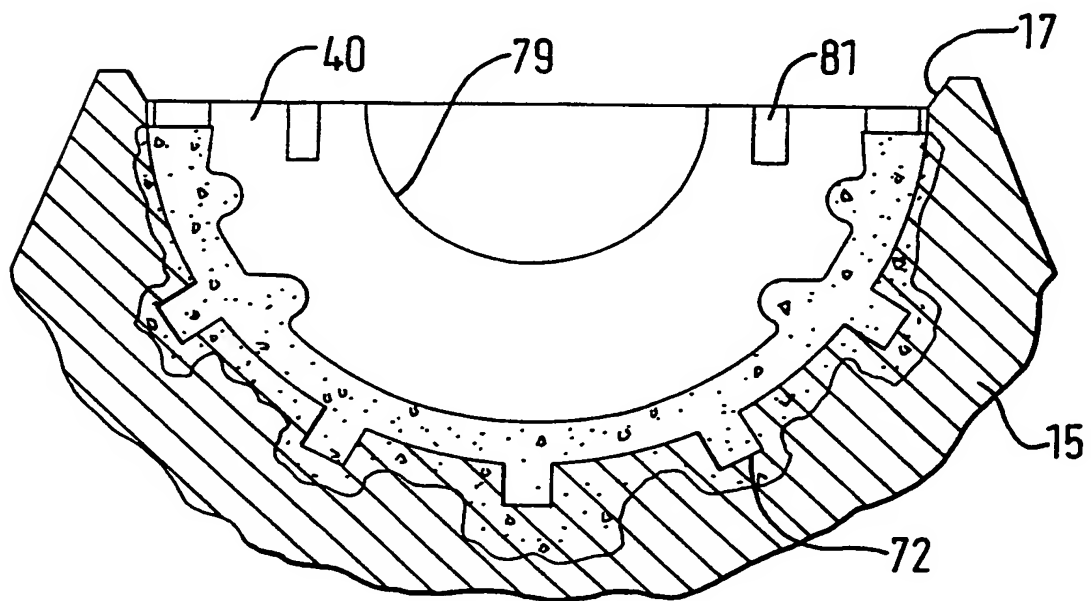
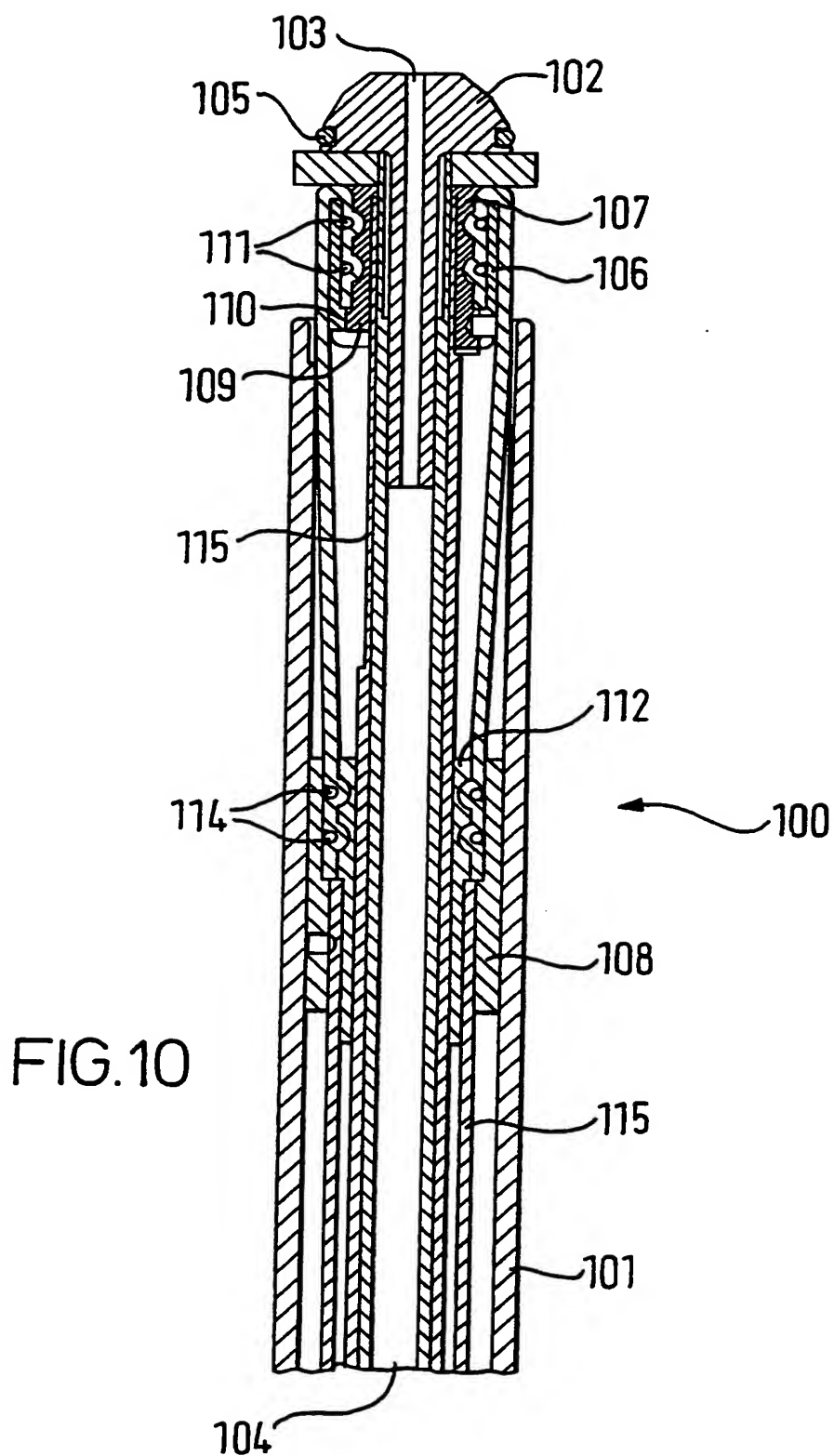
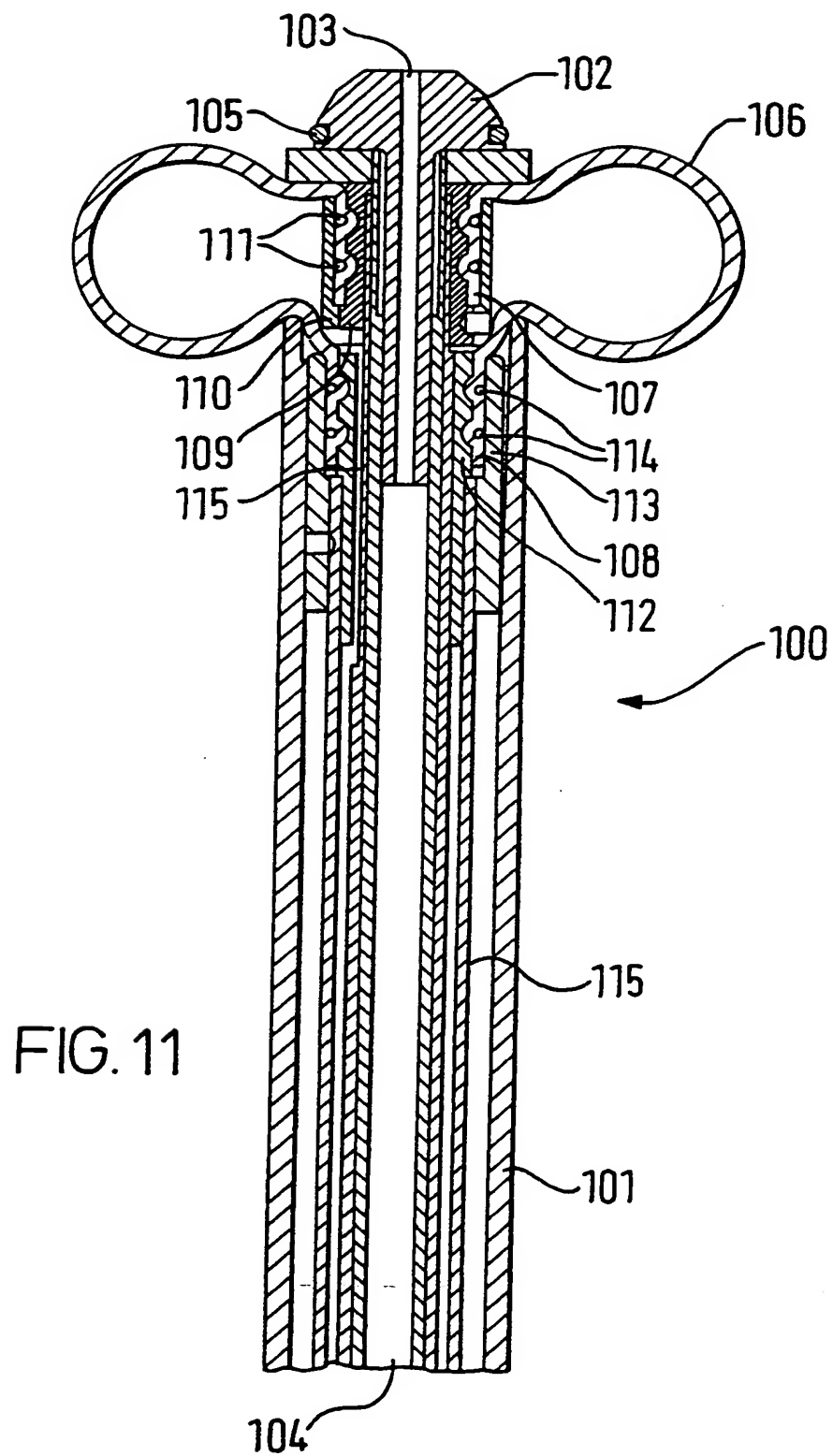


FIG. 9

7/12



8/12



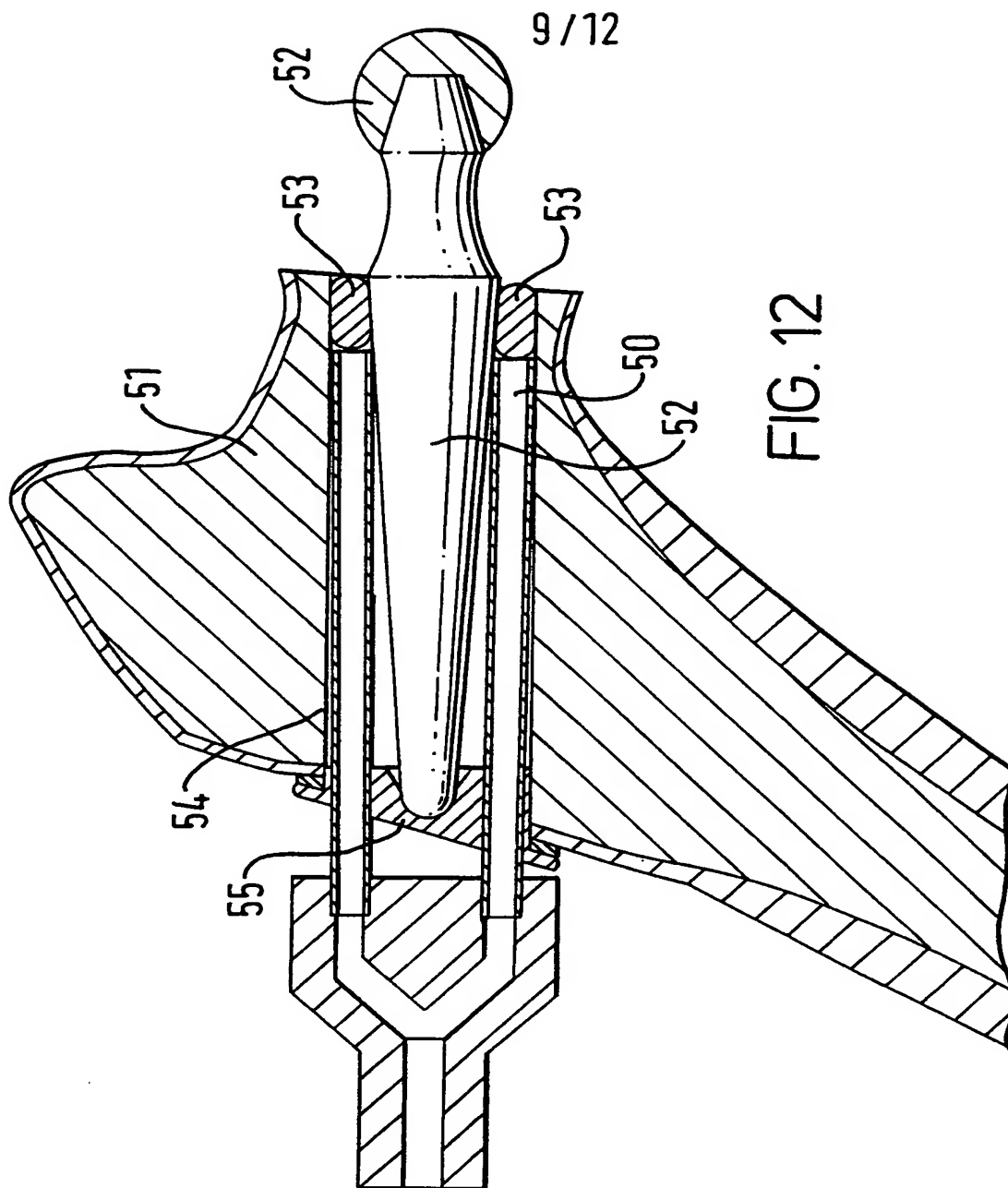


FIG. 12

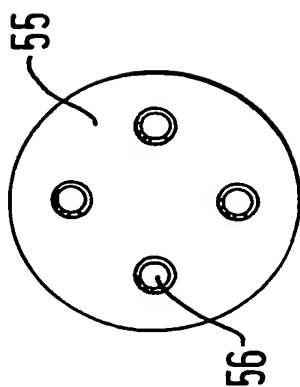


FIG. 13a

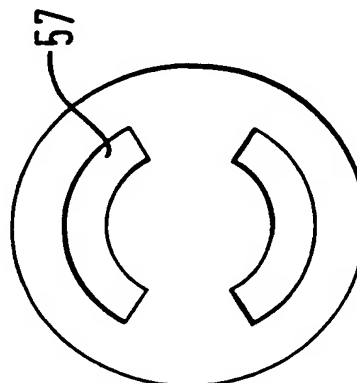
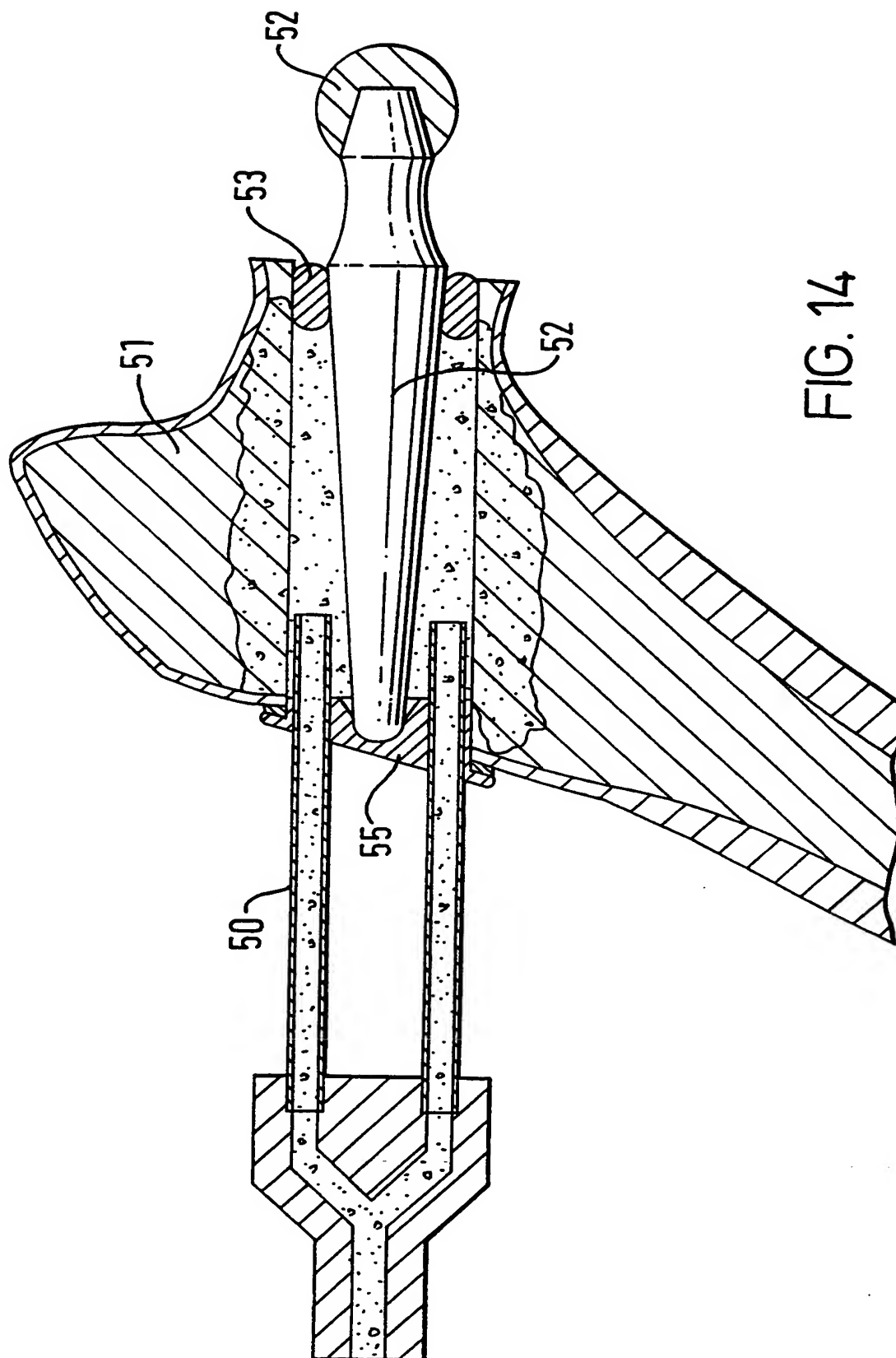


FIG. 13b

10/12



11/12

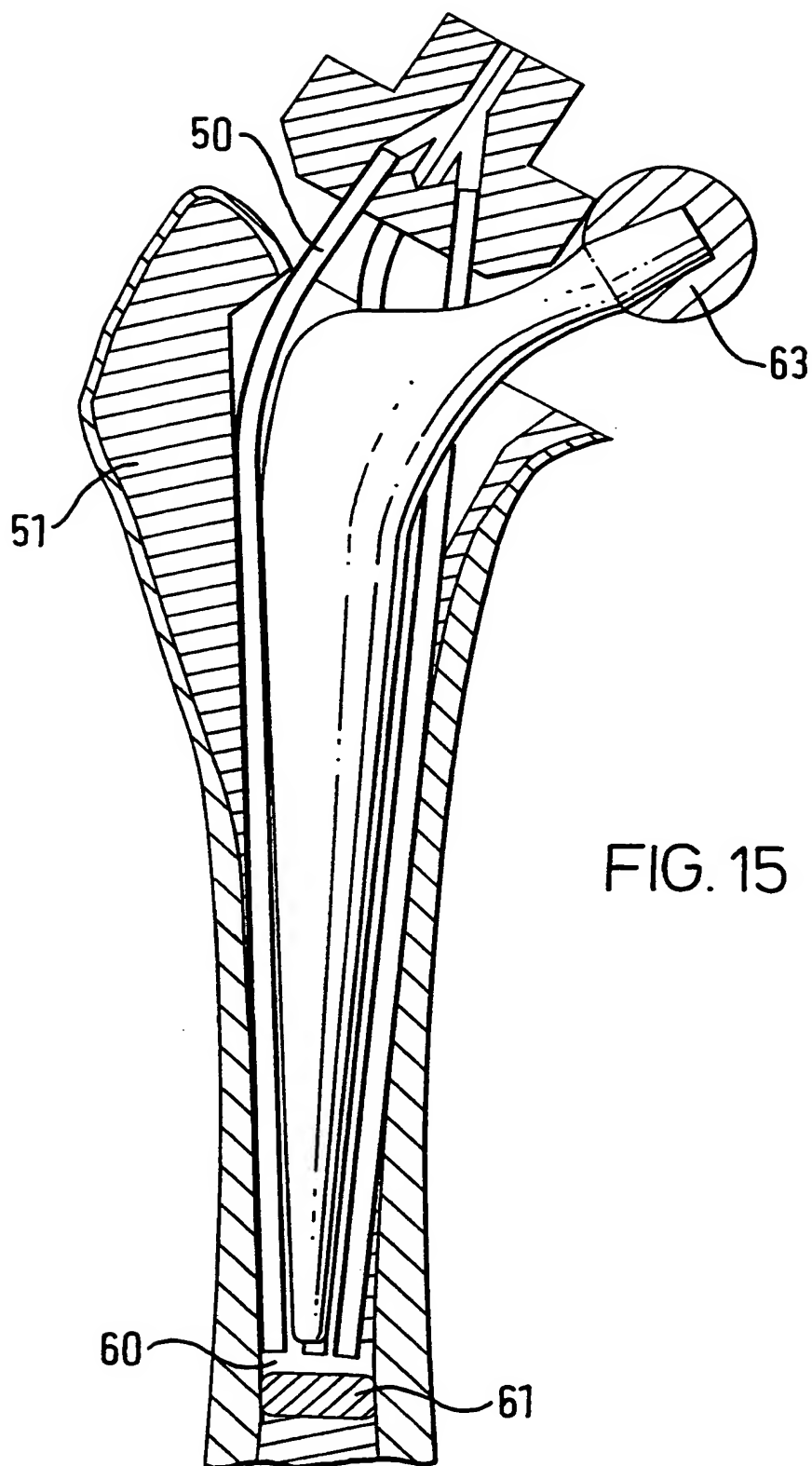


FIG. 15

12/12

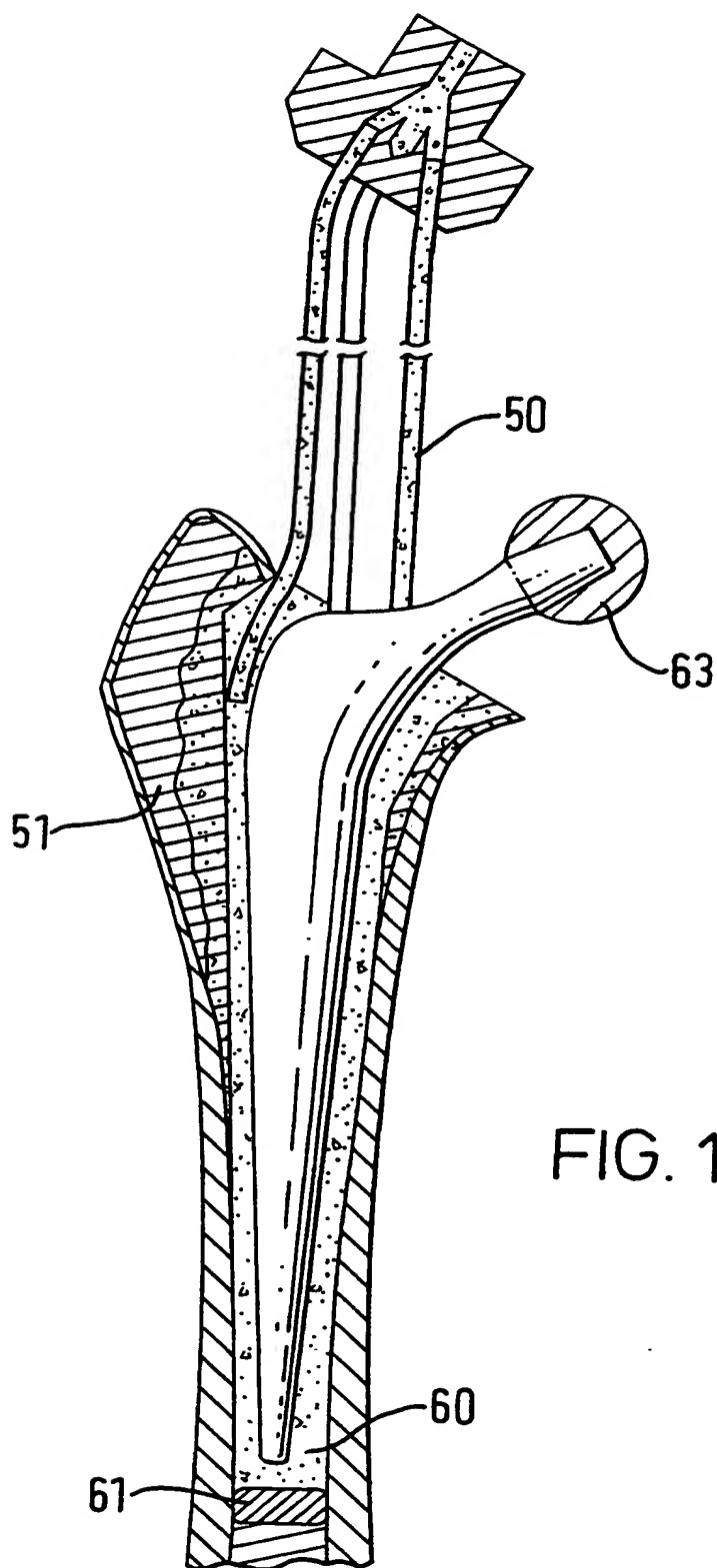


FIG. 16